

DEFINITIONS OF HEALTH LITERACY AND NUMERACY AND THEIR
RELEVANCE FOR PATIENT-PHYSICIAN COMMUNICATION AND TREATMENT
DECISION MAKING IN THE MEDICAL ENCOUNTER

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A Thesis Submitted to the School of Graduate Studies in Partial Fulfillment of the
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TITLE: Definitions of Health Literacy and Numeracy and Their Relevance for Patient-Physician Communication and Treatment Decision Making in the Medical Encounter

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Lay Abstract

Health literacy – the ability to obtain, understand, evaluate, and communicate information - is gaining increasing attention from both researchers and policymakers. This attention is important to efforts seeking to involve patients in their treatment decisions. Some of these efforts require attention to patients' health literacy, but do not make clear if numeracy (or math skills) is part of health literacy.

This research examines how health literacy and numeracy are defined. The relationship(s) that health literacy and numeracy have with the three stages of the treatment decision making process are also examined. The findings show that health literacy and numeracy have been: (1) defined and measured differently in studies, and (2) largely treated as separate concepts by researchers. The relationships between health literacy, numeracy, and the three stages of treatment decision making are also unclear because of knowledge gaps and measurement-related problems.

Abstract

Efforts by policymakers to involve patients in treatment decision making are increasing worldwide. Some of these efforts must accommodate patients with different levels of health literacy, but do not specify if numeracy is part of health literacy. This research asked, *How are health literacy and numeracy defined in the academic literature and what empirical relationship(s) do they have with the three stages of the treatment decision making process?*

I conducted a systematic review and two scoping reviews. In the systematic review, I identify definitions of health literacy used in the academic literature and interpretations possible for the most commonly used definitions. In the first scoping review, I map the empirical relationships between health literacy and the three stages of treatment decision making (information exchange, deliberation, and deciding on the treatment to implement). In the second scoping review, I map the empirical relationships between numeracy and the three stages of treatment decision making, and examine if, and how, numeracy has been mentioned in relation to health literacy.

The systematic review identified 250 different definitions of health literacy and found the most commonly used definitions open to differing interpretations. The scoping reviews revealed a lack of: (1) agreement over the definition, measurement, and handling of health literacy and numeracy in studies, and (2) overlap in the relationship(s)

examined. Health literacy and numeracy were largely treated as separate concepts. Knowledge gaps and measurement-related problems were identified.

The findings from the systematic review pose significant challenges for the measurement of health literacy and for the implementation of health literacy-related policy initiatives. The meaning(s) of health literacy must be explicated by both researchers and policymakers.

The findings from the scoping reviews indicate that the relationship(s) between health literacy, numeracy, and treatment decision making is unclear. Researchers must address the knowledge gaps and measurement-related problems identified.

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List of Abbreviations and Symbols

ACA	United States Patient Protection and Affordable Care Act
HL	health literacy
PDA	patient decision aid
PIAAC	Program for the International Assessment of Adult Competencies
SDM	shared decision making
TDM	treatment decision making
U.S.	United States

Preface

This sandwich thesis is comprised of one systematic review and two scoping reviews. Contained within this sandwich thesis is original scientific research which examines how health literacy and numeracy are defined in the academic literature as well as their respective empirical relationships with each of the three stages of the treatment decision making process (information exchange, deliberation, and deciding on the treatment to implement). For each of the three reviews, I conducted the search of academic databases, downloaded all of the records returned, extracted all relevant data, organized and analyzed the data in keeping with the adopted methodology, and wrote up the findings.

While I carried out each of the three studies, I would like to acknowledge the contributions of the following individuals. Maureen Rice provided assistance with the selection of appropriate databases and search terms for the two scoping reviews. Dr. Malcolm Weir assisted with relevance screening in the two scoping reviews. Dr. Charles, Dr. Gafni, and Dr. Entwistle were involved in the pilot testing of relevance screening criteria used in the scoping reviews. Dr. Charles assisted with the pilot testing of the data charting form used in the scoping reviews. Dr. Charles, Dr. Gafni, and Dr. Entwistle provided feedback on the manuscripts for the systematic review and on the first scoping review. The systematic review was submitted to *Patient Education and Counseling* on

June 27, 2015. The first scoping review was published by *Patient Education and Counseling* in 2015.

I would also like to acknowledge the contributions of Dr. Schwartz, Dr. McKibbon, and Dr. Yost toward the completion of the second scoping review. Each provided feedback on the findings as well as helpful comments on the writing of the corresponding manuscript. The second scoping review was submitted to *Patient Education and Counseling* on May 5, 2015. Dr. Schwartz, Dr. McKibbon, and Dr. Yost also provided feedback on the Introduction and Conclusion sections of this sandwich thesis.

Chapter 1: Introduction

This dissertation takes the form of a “sandwich thesis”. As such, it is comprised of an introductory chapter, one systematic review (submitted to *Patient Education and Counseling*), two scoping reviews (one published in, and one submitted to, *Patient Education and Counseling*), and a concluding chapter. In this introductory chapter, I introduce two key concepts – health literacy and numeracy - and describe how they intersect in recent policy developments. I also provide a brief overview of the three reviews.

Health Literacy and Numeracy

When individuals are health-literate, they tend to have a better understanding of health, health care and treatments; they are likely to live longer, healthier lives; and they tend to require fewer health care interactions and resources. The term health literacy first appeared in 1974 in S. K. Simonds’s paper titled *Health education as social policy*. In this paper, the concept was not explicitly defined. It was, however, used in the context of advocating for health education in school children (i.e., kindergarten to grade 12) as a way to promote public health.

Since 1974, the concept of health literacy has been adopted, revised and expanded in primarily two separate, but related domains; that is, the fields of medicine and public

health (Pleasant & Kuruvilla, 2008). The evolving nature of the concept of health literacy, and the lack of agreement over its definition, meaning, and measure, has “become a source of confusion and debate” (Baker, 2006, p. 878). To illustrate this lack of agreement, Table 1 presents some selected examples of definitions of health literacy that various health organizations have adopted.

Table 1: Selected examples of definitions of health literacy adopted by health organizations

<i>Organization</i>	<i>Definition of health literacy adopted</i>
World Health Organization (1998, p. 10, original italics)	Health literacy represents the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good <i>health</i> .
Public Health Agency of Canada (2014, para 1, original bolding)	In Canada health literacy is defined as “the ability to access, comprehend, evaluate and communicate information as a way to promote, maintain and improve health in a variety of settings across the life-course.”
U.S. Institute of Medicine (2004, p. 4)	The degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions. (citing Ratzan & Parker, 2000)

Beyond the lack of a unified definition, existing measures of health literacy are limited in their ability to evaluate skills; lack cultural sensitivity; contain items that are ambiguous in terms of their wording; focus on a single dimension, rather than the multiple dimensions that comprise health literacy; and have not undergone rigorous

psychometric analysis (Pleasant, MicKinney, & Rikard, 2011). With these limitations in mind, it is important to note that poor health literacy has been labelled by the U.S. government as a public health problem (Clark, 2011). Limited health literacy has been called a *silent epidemic* because of the lack of understanding shown by professionals and policymakers about the problem, and the shame which keeps the problem hidden (Clark, 2011; Institute of Medicine, 2004). Most notably:

Health literacy is typically touted as an important tool for overcoming access barriers and empowering patients to be better health care partners, and evidence indicates that higher health literacy levels are associated with better health care access and outcomes. Increasingly, *claims are also made that improving health literacy will significantly reduce the money that patients, providers, insurers, and the government currently spend on unnecessary or inappropriate treatment.* (Clark, 2011, p. 256, italics added)

According to Clark (2011, p. 256):

Inappropriate treatment includes different kinds of treatment: discretionary treatment a patient would not chose if provided complete with [sic] information or given a chance to participate in the decision, as well as the overuse of care that can be avoided with better health care management.

In the section that follows, I provide a brief overview of numeracy.

Numeracy

Important to claims made about health literacy in relation to treatment decision making, is the fact that some measures of health literacy assess numeracy (e.g., Test of Functional Health Literacy in Adults, Newest Vital Sign), while others do not (e.g., Rapid Estimate of Adult Literacy in Medicine). A lack of agreement also exists over the definition and meaning of numeracy. In this study, I have adopted the definition of numeracy put forth by the Organization for Economic Co-operation and Development's Program for International Assessment of Adult Competencies. They define numeracy as, "the ability to access, use, interpret, and communicate mathematical information and ideas, in order to engage in and manage the mathematical demands of a range of situations in adult life" (2009, p. 21).

International assessments of numeracy conducted by the Program for the International Assessment of Adult Competencies (PIAAC) indicate that poor numeracy is a worldwide phenomenon. As shown in Figure 1, and explained further in Table 2, more than half of all adults (aged 16 to 65) assessed worldwide fall at, or below, Level 2 on the PIAAC numeracy measure. This finding, in addition to concerns raised about the inadequate numeracy skills of health professionals (Eley et al., 2014; McMullan, 2010; Rao, 2008), have implications for (a) patients' ability to participate in treatment decision making; particularly, when numerical information about the risks and benefits of

treatment(s) is communicated by health professionals to patients, and (b) policies that support patients' participation in treatment decision making. Low numeracy puts at stake patients' ability to meaningfully participate in the treatment decision making process; health professionals' ability to communicate numerical information to patients in a manner that is both accurate and easily understood; and efforts to promote shared decision making in clinical practice. In the section that follows, I provide an overview of the treatment decision making framework that I have adopted in this research.

Figure 1: Numeracy proficiency among adults (aged 16-65) in 23 countries (OECD, 2013, p. 75) – Reprinted with permission

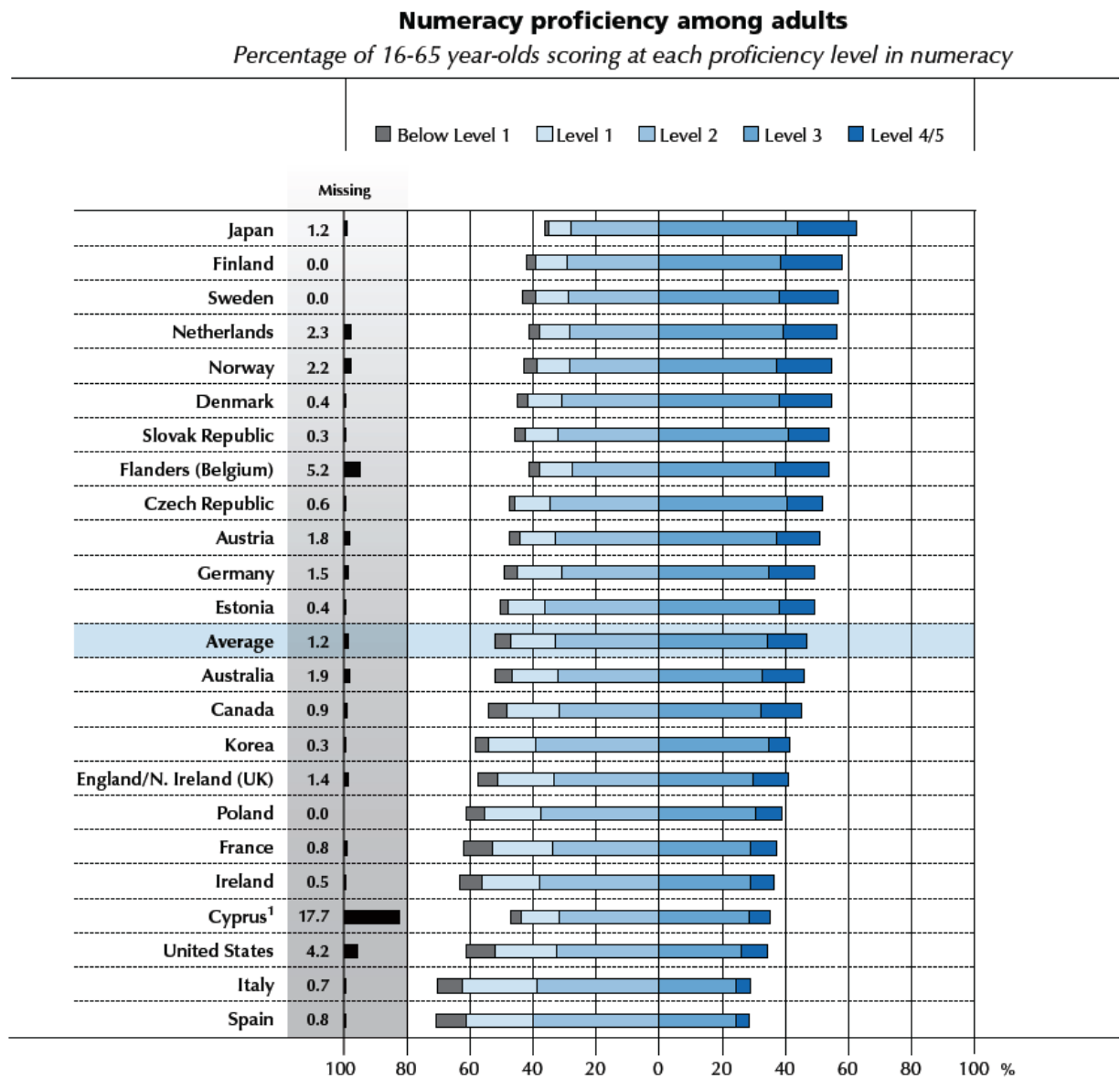


Table 2: Description of proficiency levels in numeracy (OECD, 2013, p. 76) – Reprinted with permission

Level	Score Range	Percent of adults scoring at each level (average)	The types of tasks completed successfully at each level of proficiency
Below Level 1	Below 176 points	5%	Tasks at this level require the respondents to carry out simple processes such as counting, sorting, performing basic arithmetic operations with whole numbers or money, or recognising common spatial representations in concrete, familiar contexts where the mathematical content is explicit with little or no text or distractors.
1	176 to less than 226 points	14.0%	Tasks at this level require the respondent to carry out basic mathematical processes in common, concrete contexts where the mathematical content is explicit with little text and minimal distractors. Tasks usually require one-step or simple processes involving counting, sorting, performing basic arithmetic operations, understanding simple percents such as 50%, and locating and identifying elements of simple or common graphical or spatial representations.
2	226 to less than 276 points	33.0%	Tasks at this level require the respondent to identify and act on mathematical information and ideas embedded in a range of common contexts where the mathematical content is fairly explicit or visual with relatively few distractors. Tasks tend to require the application of two or more steps or processes involving calculation with whole numbers and common decimals, percents and fractions; simple measurement and spatial representation; estimation; and interpretation of relatively simple data and statistics in texts, tables and graphs.
3	276 to less than 326 points	34.4%	Tasks at this level require the respondent to understand mathematical information that may be less explicit, embedded in contexts that are not always familiar and represented in more complex ways. Tasks require several steps and may involve the choice of problem-solving strategies and relevant processes. Tasks tend to require the application of number sense and spatial sense; recognising and working with mathematical relationships, patterns, and proportions expressed in verbal or numerical form; and interpretation and basic analysis of data and statistics in texts, tables and graphs.
4	326 to less than 376 points	11.4%	Tasks at this level require the respondent to understand a broad range of mathematical information that may be complex, abstract or embedded in unfamiliar contexts. These tasks

Level	Score Range	Percent of adults scoring at each level (average)	The types of tasks completed successfully at each level of proficiency
			involve undertaking multiple steps and choosing relevant problem-solving strategies and processes. Tasks tend to require analysis and more complex reasoning about quantities and data; statistics and chance; spatial relationships; and change, proportions and formulas. Tasks at this level may also require understanding arguments or communicating well-reasoned explanations for answers or choices.
5	Equal to or higher than 376 points	1.1%	Tasks at this level require the respondent to understand complex representations and abstract and formal mathematical and statistical ideas, possibly embedded in complex texts. Respondents may have to integrate multiple types of mathematical information where considerable translation or interpretation is required; draw inferences; develop or work with mathematical arguments or models; and justify, evaluate and critically reflect upon solutions or choices.

Treatment Decision Making

As shown in Figure 2, I have adopted the treatment decision making framework developed by Charles, Gafni, and Whelan (1999). In their framework, three pure treatment models (i.e., paternalistic, shared, informed) are situated along a continuum. Three analytic stages are also specified for each model. These three stages include information exchange, deliberation, and deciding on the treatment to implement.

Located at one end of the continuum is the *paternalistic* treatment decision making model. In this model, the minimum legally required medical information is conveyed primarily by the physician to the patient. The patient is excluded from the deliberation process. The physician alone decides on the treatment to implement.

The *informed* treatment decision model is located at the opposite end of the continuum. In this model, all medical information relevant for decision making flows largely from the physician to the patient. The patient and possibly others undertake the deliberation process without the involvement of the physician. The patient, rather than the physician, decides on the treatment to implement.

Located between the two extremes is the *shared decision making* model. In the shared model, all medical and personal information that is relevant for decision making is exchanged between the physician and patient. Unlike the other treatment models, the physician, patient, and possibly others undergo the deliberation process together. The physician and patient also decide on the treatment to implement together.

Unique to the framework are the in-between approaches which rest along the continuum between the three pure models. Also unique, is the dynamic way in which treatment decision making is conceptualized in this framework. Instead of viewing treatment decision making as a stable and linear process, “the framework makes explicit the possibility that not only can the decision-making approach used in one physician-patient interaction change in the next interaction, it can also change within a single encounter” (Charles et al, 1999, p. 658).

Figure 2: Treatment decision making framework (Charles, Gafni, and Whelan's, 1999, p. 653) – Reprinted with permission

Analytical stages	Models	Paternalistic (in between approaches)	Shared (in between approaches)	Informed
Information exchange	Flow	One way (largely)	Two way	One way (largely)
	Direction	Physician → patient	Physician ⇌ patient	Physician → patient
	Type	Medical	Medical and personal	Medical
	Amount ^b	Minimum legally required	All relevant for decision-making	All relevant for decision-making
Deliberation		Physician alone or with other physicians	Physician and patient (plus potential others)	Patient (plus potential others)
Deciding on treatment to implement		Physicians	Physician and patient	Patient

^a Illustration for an encounter focusing on the case of a (treating) physician–patient dyad. For more complex cases see text.

^b Minimum required.

Shared Decision Making

Of the treatment decision making models shown in Figure 2, there is a growing international trend toward the implementation, and in some cases legislation, of shared decision making in the clinical encounter (Frosch et al, 2011; Harter, Weijden, & Elwyn, 2011). This trend is a policy-related foci of this dissertation research because, by definition, shared decision making requires that patients' participate in the treatment decision making process.

Although variously defined in the literature, the most common conceptualization of shared decision making is that proposed by Charles et al. (1999). In their conceptualization, shared decision making has four necessary characteristics (p. 652):

1. At minimum, both the physician and patient are involved in the treatment decision-making process.
2. Both the physician and patient share information with each other.
3. Both the physician and the patient take steps to participate in the treatment decision-making process by expressing treatment preferences.
4. A treatment decision is made and both the physician and the patient agree on the treatment to implement.

Evidence to indicate the growing interest in the implantation of shared decision making can be found in issue 105 of the *German Journal for Evidence and Quality in Health Care*. This issue was dedicated entirely to examining the degree of implementation of share decision making in 13 different countries. A summary of the state of implementation in each of these 13 countries is provided in Table 3.

Review of Table 3 suggests the following. First, a lot of diversity exists in terms of the priority given to shared decision making, at various levels (research, policy, and practice), in different countries. Second, the shift from policy development to implementation reflects a growing belief that shared decision making is the “best” treatment decision making model for patients and physicians to adopt under certain circumstances. Third, the United States is the leader in terms of its efforts to implement shared decision making into practice through the passing of legislation.

Table 3: Summary of efforts to implement shared decision making in 13 countries

Country	Degree of implementation of shared decision making as per Harter and colleagues (2011)
Australia	<ul style="list-style-type: none"> • support for shared decision making exists in guidelines and policy documents, • shared decision making is strongly endorsed by consumer organizations • limited tools available for shared decision making in clinical practice • limited resources and infrastructure • no clear strategy to support implementation of shared decision making within the healthcare system
Brazil	<ul style="list-style-type: none"> • research interest in shared decision making in health care is slowly developing • shared decision making does not exist in routine clinical practice • At early stage in terms of developing patient decision support
Canada	<ul style="list-style-type: none"> • shared decision making initiatives in different parts of the country, the most advanced provincial initiative is in Saskatchewan • Patient Decision Aids Research Group in Ottawa and Ontario maintains a public inventory of decision aids • professional interest in shared decision making in Canada is not yet widespread
Chile	<ul style="list-style-type: none"> • some interest in strengthening patients’ and professionals’ involvement in shared decision making • little has been done to support shared decision making • research activities limited to one academic institution. • decision support tools and coaching interventions focused on one disease
France	<ul style="list-style-type: none"> • a social demand exists for more healthcare user information and greater patient participation, but has not been translated into a body of research or into clinical practice • a few research projects in oncology have been developed, some use decision aids • a shared decision making observatory has been proposed

Country	Degree of implementation of shared decision making as per Harter and colleagues (2011)
Germany	<ul style="list-style-type: none"> • active support for shared decision making from health policy, federal institutions, and health insurers • training programs for healthcare professionals have been developed and partially implemented in medical schools and post-graduate activities • development and implementation of decision support tools is low
Israel	<ul style="list-style-type: none"> • few organized programs promote shared decision making among medical professionals or public • minimal governmental support of shared decision making-related research • initiatives to promote shared decision making (e.g., decision aids) are in infancy
Italy	<ul style="list-style-type: none"> • importance of patient participation recognized by National Health Plan, regional and local health authorities in general terms. • few examples of decision aids designed for patients according to shared decision making concepts • some elements of shared decision making found in some medical school courses
Netherlands	<ul style="list-style-type: none"> • research projects on shared decision making are funded, but a coordinated research agenda does not exist • governmental healthcare portal hosts a range of patient decision aids, but missing impact on practice to date. • limited effort to date on training professionals in shared decision making. • a platform for shared decision making to be launched to coordinate disparate research initiatives
Spain	<ul style="list-style-type: none"> • National Health System funding development of decision aids • shared decision making and decision aids not included in health services and professional curricula • no standardized implementation to support decisions in routine care • most professionals unfamiliar with patients' rights regarding the making of health decisions
Switzerland	<ul style="list-style-type: none"> • no national program promoting shared decision-making • two decision support tools have been developed • Swiss doctors acknowledge that shared decision making is important, but has yet to be translated into practice
United Kingdom	<ul style="list-style-type: none"> • numerous active research groups • government in 2010 included shared decision making as a central policy, but limited funds were subsequently allocated • National Health Service in England commissioned NHS Direct to host web-based decision aids, but impact on clinical practice unclear
United States	<ul style="list-style-type: none"> • provisions supporting shared decision making and patient decision support in health care reform legislation • several states have passed legislation incorporating shared decision making • research supported by a range of organizations

Country	Degree of implementation of shared decision making as per Harter and colleagues (2011)
	<ul style="list-style-type: none"> different organizations developing decision support interventions

The growing shift to implement shared decision making in practice is important given the considerable debate among researchers about the conditions and extent to which patients should be encouraged to participate in decisions about their care (Coulter, 2005). Concerns arise about the validity of measures used to assess shared decision making (Scholl et al., 2011) and patients' participation/involvement in treatment decision making (Entwistle et al., 2004, 2001). Significant practice barriers to the implementation of shared decision making have been identified (Legare, Ratte, Gravel, & Graham, 2008). These barriers include, but are not limited to, a lack of awareness about, and familiarity with, shared decision making, a lack of agreement on the components of shared decision making, and a perception among health professionals that shared decision making will not lead to improved outcomes. Evidence also suggests that preference for an active role in decision making is influenced by multiple factors; such as, age, gender, level of education, previous experience with illness and medical care, and the type of decision that needs to be made (Say, Murtagh, & Thomson, 2006). In the section that follows, a definition of patient decision aids is provided and I discuss their relevance to shared decision making.

Patient Decision Aids

Parallel to the shift to implement the use of shared decision making, is a growing international movement to promote the implementation of patient decision aids in clinical practice (Harter, van der Weijden, & Elwyn, 2011). Patient decision aids have been defined by the International Patient Decision Aid Standards Collaboration (2012, para 1) as, “tools designed to help people participate in decision making about health care options. They provide information on the options and help patients clarify and communicate the personal value they associate with different features of the options.”

The academic literature shows a lack of consensus over what role, if any, patient decision aids play in shared decision making. Some authors report that patient decision aids *facilitate* the shared decision making process (O’Connor, Llewellyn-Thomas, & Flood, 2004). Others seem to equate the use of patient decision aids with shared decision making, despite citing models of shared decision making that do not explicitly incorporate the use of patient decision aids (Kim et al., 2001). The International Patient Decision Aid Standards Collaboration (2012, para 2, italics added), on the other hand, states that patient decision aids, “prepare patients to make *informed*, values-based decisions with their practitioner.”

Aside from the lack of consensus over the role(s) they play, barriers to the implementation of patient decision aids in clinical practice are present. Some of these barriers include a perception among physicians that patient decision aids are too complex, only appropriate for certain patients, and time consuming (Graham et al., 2003). Physicians have also reported that the use of patient decision aids would be related to,

among other things, their patients' literacy levels (Graham et al., 2003). Given the nature and scope of the issues that have been identified in regards to the implementation of shared decision making and patient decision aids in clinical practice, and because of the importance given to shared decision making in the 2010 U.S. Affordable Care Act, provisions that appear in the Act deserve attention. I provide an overview of these provisions is provided in the section that follows.

Intersection of health literacy, shared decision making, and patient decision aids in the 2010 U.S. Patient Protection and Affordable Care Act

On March 23, 2010, the U.S. Patient Protection and Affordable Care Act (henceforth referred to as the Act) was signed into law by President Barack Obama. The Act contains provisions to expand U.S. citizens' access to health insurance, contain health care costs, and improve the quality and performance of the health care delivery system (Kaiser Family Foundation, 2011). Given the aims of the Act, McDonough's¹ (2011) reflections on its enactment are worth noting:

There will be controversy, threats, financial stress, modifications, deletions, improvements, and limits in many directions. Many Americans' lives will be saved and improved and more than a few will be burdened. There will be surprise aplenty, welcome and distressing. At the heart of it will be the perpetual effort to shape and reshape a health care system to meet the values and expectations of a diverse and divided public. The ACA [Affordable Care Act] is a landmark law, on par with the Social Security Act of 1935 and the Medicaid law of 1965. (p. 5)

¹ From John E. McDonough's (2011) book titled, *Inside National Health Reform*. In writing this book, McDonough represented both legislative parties, wrote extensive notes throughout the legislative process, "conducted more than 125 interviews with both congressional and administration staffers, and pored through the copious literature on the health reform process and the complex U.S. health care system itself" (p. xii).

In a chapter dedicated to Title III of the Act, McDonough (2011) also states:

The ACA [Affordable Care Act] took every idea on how to reduce health care spending, public and private, and pushed as far as the political system would tolerate in 2009 and 2010. Some of these innovations will fail, either completely or mostly. Some will succeed, far beyond the estimates calculated by the CBO [Congressional Budget Office]. Some of these innovations will be altered by Congress in the coming years, and no one will know how they might have otherwise worked. (p. 178)

Title III of the Act is of interest to this research; in particular, sub-section 936 which is titled “Program to Facilitate Shared Decisionmaking” [sic]. In this sub-section, provisions exist that support the development, updating, and production of patient decision aids that “present up-to-date clinical evidence about the risks and benefits of treatment options” in a manner that, among other things, “reflects the varying needs of consumers and diverse levels of *health literacy*” (p. 529, italics added). In a separate section of the Act, health literacy is defined as “the degree to which an individual has the capacity to obtain, communicate, process, and understand health information and services in order to make appropriate health decisions” (p. 1252). These provisions deserve attention for the following reasons.

First, the provisions imply that health literacy is important to treatment decision making. Second, the provisions do not specify whether or not numeracy is considered to be a component of health literacy. This lack of specification is important given that some measures of health literacy assess numeracy, while others do not. Inadequate numeracy has also been identified as a problem in both patients and health professionals (Eley et al., 2014; McMullan, 2010; Rao, 2008). Lack of attention to numeracy thus has important

implications for patients' participation in treatment-related decisions; particularly, decisions that rely on numerical information communicated to patients by health professionals or decision aids. As such, this doctoral research sought to answer: *How are health literacy and numeracy defined in the academic literature and what empirical relationship(s) do they have with the three stages of the treatment decision making process?* The objectives are to: (1) identify priority areas for research, and (2) inform policy and practice as it pertains to the use of shared decision making, or patient decision aids, in ways that accommodate the needs of patients with different levels of health literacy and numeracy.

In the sections that follow, I describe the three inter-related studies that address the main research question. I outline the research question(s) and methods adopted in each study. I establish the link between the three studies and discuss the expected contributions of this research.

Chapter 2 - A review of health literacy: definitions, interpretations, and implications for research, policy, and practice

Previous attempts to identify, analyze, and in some cases classify, different definitions of health literacy have focused on a small set of highly cited definitions. Less attention has been paid to the words, phrases, and underlying assumptions contained in definitions of health literacy that may be open to different, and potentially problematic, interpretation(s). Chapter 2 thus seeks to answer the following:

1. To what extent are different definitions of health literacy used in the academic literature?
2. What are the similarities and differences across definitions?
3. What kinds of interpretations are possible for the most commonly used definitions?

To answer these questions, I conducted a systematic review (Petticrew & Roberts, year) and critical analysis (Hughes, 1999) of definitions of health literacy extracted from articles indexed in the Medline database between the years 2007 and 2013. Through this review, I identified 250 different definitions of health literacy. After an analysis of their wording, I grouped these definitions into three categories (1) most commonly used (n = 6); (2) modified versions of the most commonly used definitions (n = 133); and (3) other definitions (n = 111). A critical analysis of the most commonly used definitions found them to be open to multiple interpretations, and reflect underlying assumptions that are not always justifiable.

Chapter 3 - Empirical relationships between health literacy and treatment decision making: A scoping review of the literature

Relevant to the growing trend to implement shared decision making and the use of patient decision aids in clinical practice, is the notion that health literacy is important to, or influences, treatment decision making. Examples of claims to support this notion can be found in statements such as, “health literacy is *required* for patients to *effectively* use decision aids” (McCaffery et al., 2012, p. 2) and “[I]mproving health literacy has the

potential to *promote*”, among other things, “*more informed decision making*” (Bann et al., 2012, p. 200).

Provisions found under sub-section 936 of the 2010 U.S. Patient Protection and Affordable Care Act reflect or re-inforce the notion that health literacy is important to treatment decision making. Under this sub-section, provisions support the development, updating and production of patient decision aids in ways that, among other things, reflect consumers with diverse levels of health literacy. Given the uncertainties that exist around how to best enable patient participation, Chapter 3 seeks to answer: *What is known from the existing literature about the empirical relationship(s) between health literacy and the three stages of the treatment decision making process (information exchange, deliberation, and deciding on the treatment to implement)?*

To answer this question, I conducted a scoping review of the literature using the approach described by Arksey and O'Malley (2005). To identify primary studies relevant for answering the scoping review question, four academic databases (Medline, Embase, CINAHL, ERIC) were searched and returned 2,772 records. After de-duplication and two levels of relevance screening, a decision was made by the research team (i.e., Leslie Malloy-Weir, Dr. Charles, Dr. Gafni, and Dr. Entwistle) to remove from this review on health literacy, and examine in a separate scoping review, studies that examined numeracy. This decision was based on the fact that the term health literacy, as opposed to numeracy, has been explicitly mentioned in: (1) statements made in the academic literature which link it to treatment decision making and the use of patient decision aids, and (2) provisions in the 2010 U.S. Patient Protection and Affordable Care Act that

pertain to the development of patient decision aids. The decision to examine numeracy in a separate scoping review was also based on the fact that some of measures of health literacy assess numeracy, while others do not. Following this decision, a third level of relevance screening was applied to records and 41 primary studies were included in this health literacy study. Relevant data from these 41 studies were charted, organized, compared, and summarized.

By mapping the existing literature, I found a lack of agreement over the definition(s) and measure(s) of health literacy adopted by researchers in the area of treatment decision making. This finding both links to, and supports, the findings in Study 1. I identified important gaps in knowledge. I also identified multiple methodological problems in the included studies. In the section that follows, I provide an overview of the review that focused on numeracy.

Chapter 4 - Empirical relationships between numeracy and treatment decision making: A scoping review of the literature

Poor numeracy is widespread in many countries and has been identified as a problem among both patients and health professionals. This problem has important implications for efforts to involve patients in treatment decision making; particularly, when numerical information about the risks and benefits of treatment is communicated by health professionals to patients. Chapter 4 thus sought to answer: *What is known from the existing literature about the empirical relationships about numeracy and the three stages of the treatment decision making process?* This study also examines: *How has numeracy*

been mentioned in relation to health literacy by researchers in the area of treatment decision making?

To address these questions, a second scoping review was conducted of the 38 numeracy-related studies not considered in Study 2. Study 3 links to Study 1 by examining how numeracy has been defined and mentioned in relation to health literacy by researchers in the area of treatment decision making. Study 3 links to Study 2 in that both scoping reviews examine empirical relationships between the main concepts (i.e., numeracy and health literacy) and the three stages of the treatment decision making process. Since both of these scoping reviews map data reflective of the same temporal period, and draw on the same academic databases, direct comparisons can be made of the similarities and differences in the findings.

Similar to Study 2, Study 3 found a lack of agreement over the definition(s) and measure(s) of numeracy adopted by researchers in the area of treatment decision making. Important gaps in knowledge were uncovered. A number of methodological problems were identified. The findings also suggest that numeracy and health literacy have largely treated as separate concepts by researchers in the area of treatment decision making.

Summary

This doctoral research sought to answer: *How are health literacy and numeracy defined in the academic literature and what empirical relationship(s) do they have with the three stages of the treatment decision making process?* To address this question, I undertook three separate, but inter-related studies. In the first study, I conducted a

systematic review and critical analysis of definitions of health literacy. In the second study, I performed a scoping review of empirical relationships between health literacy and the three stages of the treatment decision making process. In the third study, I undertook a second scoping review to examine empirical relationships between numeracy and the three stages of the treatment decision making process. In these reviews, fundamental questions are raised and priority areas for research are identified. The findings will guide future research and will inform relevant policy and practice.

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Preface

The study presented in Chapter 2 has been submitted to *Patient Education and Counseling*. This study challenges ideas about the extent to which different definitions of health literacy are found in the academic literature. The findings show a significant lack of agreement over the definition of health literacy and reveal potentially problematic interpretations for the most commonly used definitions. Important questions are raised about how definitions of health literacy should be adopted and interpreted for use in policy.

To carry out this study, I performed all of the searches of Medline. I screened all of the records returned for relevance. I extracted all of the definitions of health literacy contained in the records returned. I transferred the extracted definitions into a matrix for organizational and analytic purposes. I grouped the definitions into three categories based on their wording. I performed a critical analysis of the most commonly used definitions of health literacy. I wrote multiple iterations of the manuscript. Dr. Charles, Dr. Gafni, and Dr. Entwistle contributed to the critical analysis component of the study and provided feedback on the manuscript. The version of the manuscript that was submitted to *Patient Education and Counseling* appears in Chapter 2.

Chapter 2: A review of health literacy: definitions, interpretations, and implications for research, policy, and practice

Abstract:

Objective: To determine the extent to which different definitions of HL are used in the academic literature, the similarities and differences across definitions, and possible interpretations for the most commonly used definitions.

Methods: A systematic review of articles indexed on MEDLINE between 2007 and September, 2013 was undertaken to systematically identify and compare definitions of HL used in the academic literature. The most commonly used definitions were critically analyzed to examine the kinds of interpretations that are possible.

Results: In total, 250 different definitions of HL were identified. These were grouped into three categories: (1) most commonly used definitions (n = 6); (2) modified versions of most commonly used definitions (n = 133); and (3) “other” definitions (n = 111). The most commonly used definitions of HL were found to: (1) be open to multiple interpretations, and (2) reflect underlying assumptions that are not always justifiable.

Conclusion: The findings pose significant challenges for the development, implementation, and evaluation of HL-related policy initiatives and for the development of HL measures.

Practice implications: Attention is needed to the ways in which differing definitions and, potentially problematic, interpretations of HL may affect patient care and the delivery of HL-related policy initiatives.

1.0 Introduction

How terms are defined (or not defined), interpreted, and operationalized has important implications for the delivery of healthcare and health policy-related initiatives. As such, various researchers have sought to bring attention to policy-relevant terms for which different definitions or meanings exist; for example, medical necessity[1], shared decision making [2], health governance [3], and health disparities [4].

This review focuses on the different definitions of “health literacy” - a term which has garnered increasing attention in the academic literature. To illustrate, a search of Medline (Ovid) using “health literacy” as a keyword returns 50 records published in the decade 1991-2000, compared with 1,310 in the decade 2001-2010, and 891 in the two years 2011-2012. Health literacy (HL) has also become more prominent on the health policy agendas of a number of countries, and efforts to promote it have multiplied. It appears, for example, in the 2010 U.S. Patient Protection and Affordable Care Act in provisions that support the development and testing of decision aids for patients with, among other things, diverse levels of HL.

Given these developments, it is notable that, in 2006, Baker argued that the term HL had “come to mean different things to various audiences” [5,p878]. He examined two examples of different definitions of HL to support his argument. Other authors have identified, analyzed, and in some cases classified, different definitions of HL in order to help clarify its meaning; propose a new or integrated definition of HL; and/or develop a conceptual model of HL [6-9]. However, these authors tend to focus on a small set of highly cited definitions, and pay little explicit attention to words, phrases, and underlying

assumptions that may encourage differing, and potentially problematic, interpretations. Such attention is important because definitions and interpretations have practical implications, and the existence of different definitions of HL, and the interpretations that may be possible for any given definition, may create challenges for the development, implementation, and evaluation of HL-related policy initiatives. This review, therefore, sought to answer the following:

1. To what extent are different definitions of HL used in the academic literature?
2. What are the similarities and differences across definitions?
3. What kinds of interpretation are possible for the most commonly used definitions?

2.0 Methods

2.1 Design

A systematic review of definitions of HL was performed using the approach described by Petticrew and Roberts [10]. The critical appraisal component was confined to the definitions of HL found to be most commonly used in the academic literature.

2.2 Search strategy and relevance screening to identify articles for inclusion in the systematic review

Our search strategy followed that used by Ishikawa and Yano [9]; that is, we searched MEDLINE using the key word “health literacy”. MEDLINE is the “world’s most comprehensive source of life sciences and biomedical bibliographic information” [11,para1]. We restricted our search from January 1, 2007 to September 25, 2013 to

capture definitions of HL published after Ishikawa and Yano's [9] review. This search returned a total of 1,882 empirical, conceptual, and review articles. After de-duplication, 1,749 articles remained - 167 of the articles were published in 2007; 153 in 2008; 237 in 2009; 327 in 2010; 432 in 2011; 326 in 2012, 107 in 2013 (up to September 25).

All of the articles were screened for relevance using a two-step process. In the first step, the first author used the "find" key to locate any mention of the term "HL" in either the abstract or body of PDF files of articles, or visually scanned articles for the same. Any article that contained the term "HL" was included at this step. A total of 1,606 articles mentioned HL in the abstract or main text and were passed to the next step of our review. One hundred and forty-one articles were indexed on MEDLINE under the keyword "HL" but did not mention the term HL in the abstract or body of the paper. These 141 articles were excluded at this step as well as two articles that could not be retrieved through the McMaster University library.

In the second step of relevance screening, the remaining 1,606 articles were read by the first author to determine whether or not a definition of "HL" was provided and/or cited by the author(s) in either the abstract or body of the article. The *Oxford Advanced Learners Dictionary's* [12,p401] definition of the term "definition" (i.e., "an explanation of the meaning of a word or phrase, especially in a dictionary; the act of stating the meanings of words and phrases") was used to guide this assessment. Any one or more statement(s) of, or explanation of, the meaning of the term "health literacy" was thus considered to be a definition of HL. A total of 774 articles contained one or more definitions of HL and 832 articles did not.

2.3 Abstraction, organization, and analysis of definitions

A matrix [13] was constructed to facilitate the systematic extraction of key information about the definitions of HL from each article, and to display and organize the different definitions. As shown in Table 1, for each article containing a definition of HL, the journal title was entered in the first column of the matrix. The definition(s) of HL, together with the cited reference source of the definition, was entered in the second column. This reference source, where available, was located and reviewed by the first author and the definition of HL from this source was entered into the third column. This made it possible, in the fourth column, to judge whether or not the definition entered into the second column was the ‘same’ as, or a ‘modified version’ of, the definition entered into third column.

Insert Table 1 here

As each definition of HL was extracted, the wording used in each was compared to the wording used in definitions already entered into the matrix in Table 1. Definitions that were identical in wording to those already entered into the matrix were grouped in the same row as that definition along with their cited sources. Definitions that differed in terms of their wording were assigned their own row in the matrix. This allowed for a numerical count of: (a) how often any given definition of HL was used, and (b) the different definitions of HL used in the academic literature.

To examine the similarities and differences in the wording used across definitions of HL, row by row comparisons of the wording used in definitions were made. Analytic

comments arising from these comparisons were entered into the fifth column in the matrix. The results of the comparative analysis, along with the frequency with which each definition of HL appeared in the academic literature, and their origins, were then used to create the following three categories: (a) definitions that appeared identically worded a total of five or more times in our sample (now referred to as the most commonly used definitions of HL); (b) modified versions of the most commonly used definitions, defined as those that were similar, but not identical, in wording to those identified in the first category; or (c) “other” definitions of HL, defined as those that did not fit into either of the first two categories.

To answer the third research question, a critical analysis [14] was performed. This analysis involved the research team asking three questions of the most commonly used definitions: (1) *What does the definition imply a (more) health literate person is?* This question was asked in order to identify one possible implied meaning of each definition. (2) *Are there words in the definition that are vague or ambiguous?* This question was asked in order to facilitate consideration of how the definitions could be open to different interpretations. (3) *What assumptions are inherent in the definition?* This question was asked in order to identify implicit or explicit statements, beliefs, or relationships in definitions that may be open to question (e.g., if not fully supported by empirical research). The first author’s answers to these questions were entered into column five of Table 3 and then reviewed, and in some cases expanded upon, by the other authors.

3.0 Results

3.1 To what extent are different definitions of HL used in the academic literature?

In total, **250 different definitions** of HL were extracted from the 774 articles included in this review. These 250 definitions were grouped as follows: (a) “most commonly used definitions” of HL (n = 6); (b) modified versions of the most commonly used definitions (n = 133); and (c) “other” definitions of HL (n = 111).

Table 2 column one presents the six most commonly used definitions of HL in the academic literature. As shown in Table 2, Ratzan and Parker’s [15] definition was the most commonly used, followed by the definitions put forth by the World Health Organization or WHO [16]; the Ad Hoc Committee, American Medical Association or AMA [17]; Zarcadoolas et al.[7]; Kickbusch et al. [19]; and Rootman and Gordon-El-Bihbety [20].

Examples of “modified versions of the most commonly used definitions” are listed in column two of Table 2. Given that Ratzan and Parker’s [15] definition of HL was the most commonly used in the academic literature, it is not surprising that more modified versions of this definition were found (n = 87) than any others.

Examples of “other” definitions of HL are provided in column three of Table 2. As shown in column three of Table 2, the number of “other” definitions increased in 2010 and 2012.

3.2 What are the similarities and differences across definitions?

A comparison of the most commonly used definitions of HL revealed variability in terms of the number and types of abilities (or skills) and/or actions believed to comprise HL; the context and/or timeframes in which the various abilities and/or actions are believed to be important; and what each implies a health literate person is. Moreover, while some abilities, such as the ability to “obtain” and “understand”, were common to four of the six definitions they were mentioned in terms of their application to different things; such as, “*basic health information and services*” [15] information” [16,20], and “*health information and concepts*” [18]. The actions associated with HL, and the implied sources of the value of HL (i.e., what HL was deemed useful for), also varied across definitions; for example, “to make appropriate health decisions” [15], to “promote and maintain good health” [16], “to function in the health care environment” [17], “to make informed choices, reduce health risks and increase quality of life” [18], and “to promote, maintain, and improve health” [20].

A comparison of the most commonly used definitions of HL to the modified versions of the same definitions revealed other notable findings. First, there was some consistency with respect to the terms and/or phrases that authors opted to delete, modify, and retain from the most commonly used definitions. In general, authors tended to *retain* the skills (or abilities) specified in the most commonly used definitions of HL. Statements or phrases that preceded the skills (or abilities) tended to be *deleted* while descriptors of the purposes to which HL was put tended to be *modified*. For example, the WHO [16] defined HL as, “...the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which

promote and maintain good health.” Bell [21,p2] cited the WHO publication but defined HL as “a patient's ability to gain access to, understand, and use information to improve health.” It is evident that Bell [21]: (1) *deleted* the phrase “the cognitive and social skills which determine the motivation”; (2) *retained* the skills (or abilities) “gain access to, understand, and use information”; and (3) *modified* the phrase “in ways that promote and maintain” to “to improve”. The word “individuals” was also *modified* by Bell to “a patient’s”.

Similar to the most commonly used definitions of HL, a within group comparison of the 111 “other” definitions of HL revealed variability in terms of the number and types of skills (or abilities) specified and/or actions believed to comprise HL. Of the types of skills specified, however, “understanding” appeared most frequently – appearing in 60 of 111 (or 54%) of “other” definitions. Within these 60 definitions, “understanding” was mentioned in association with 31 different types of information. The word “knowledge” appeared in 14 “other” definitions, but did not appear in any of the most commonly used definitions of HL. Within these 14 “other” definitions, however, different types of knowledge were specified. Finally, some “other” definitions of HL included the specification of a more advanced set of skills and/or actions than those identified in the first two categories of definitions. For example, the ability to, “negotiate complex health care systems” [22,p12]. The reason(s) for the specification of these skills and/or actions was (were) not provided by the author(s).

Insert Table 2 here

3.3 What kinds of interpretation are possible for the most commonly used definitions?

Table 3 summarizes the critical analysis of the most commonly used definitions of HL. It illustrates how different interpretations of definitions are possible due to the presence of vague/ambiguous wording and/or the presence of underlying assumptions that may generate misunderstandings. For example, it is unclear what authors mean by: “obtain” [15], “process” [15], “basic health information and services” [15], “basic reading and numerical skills” [17], “evaluate” [18,20], etc. While the meaning(s) of these terms may seem obvious at first glance, the entries in column five of Table 3 suggests otherwise. Unspecified “basic health information” is problematic because it is unclear what counts as “basic”. Also left open, are the source, type, amount, applicability, acceptability, and credibility of the “health information” that is referred to. Likewise, terms such as “needed” [15], “comprehend” [15,18], “understand” [15,16,20], “appropriate” [15], and “sound” [19] imply a need for interpretation involving context sensitivity, and/or value judgments, but do not make clear whose interpretation, context assessments, and/or value judgments will be used.

In column three of Table 3, sources of ambiguity in the commonly used definitions of HL are identified. The ambiguity in Ratzan and Parker’s [15] definition arises in part from a grammatical issue: it is unclear whether or not the phrase “needed to make appropriate health decisions” refers to the “basic health information and services” that precedes it, and/or whether or not an individual needs to make “appropriate health decisions” in order to be considered health literate. Also ambiguous, is whether or not the skills and/or actions that comprise HL in both Ratzan and Parker’s [15] definition, and

other commonly used definitions of the term, are viewed as necessary or sufficient conditions to achieve HL.

Further, all of the commonly used definitions reflect underlying assumptions that may not always be appropriate or justifiable. As shown in column five of Table 3, both the WHO's [16] and Rootman and Gordon-El-Bihbety's [20] definitions of HL imply that information can be used to promote or maintain health. Zarcadoolas et al.'s [18] definition implies that health information and concepts can be used to reduce health risks and increase quality of life. While these assumptions may hold in some contexts, they may not hold in others; for example, for individuals that suffer from terminal or degenerative conditions, and for those whose health is negatively influenced, or constrained, by structural barriers in society.

Potentially problematic underlying assumptions can also be found in Ratzan and Parker's [15] and Kickbusch et al.'s [19] definitions of HL. In Ratzan and Parker's [15] definition, there is an assumption that a relationship exists between the "capacity to obtain, process, and understand health information and services" AND the making of "appropriate health decisions", and Kickbusch et al.'s [19] definition equates HL with the making of "sound health decisions in the context of everyday life". Again, while these assumptions may be valid in some contexts, and for some people, health-related decision making is, in fact, influenced by multiple factors; including, but not limited to, personal values and beliefs, life context, and the acceptability of the decision making options [23]. What can be considered to be "sound" and "appropriate" can also be judged on different criteria.

Finally, as shown in column six of Table 3, the wording used in three of the most commonly used definitions can imply that the onus of achieving HL is on the “individual” [15,16,18]. The authors, and users, of these definitions may not mean to imply this, but the wording used in these definitions does not rule out this interpretation. This leaves scope for failure to recognize individual-level factors (e.g., poor health) and structural-level factors (e.g., language barriers, lack of health insurance, lack of access to a family physician, poor communication and limited (or overly complicated) information provision by health professionals, etc.) that may: (a) not be easily modified by individuals, and (b) limit, for example, an individual’s ability (or capacity) to obtain, process, and understand basic health information and services.

Insert Table 3 here

4.0 Discussion and Conclusion

4.1 Discussion

This review shows that there has been a significant increase in the number of different definitions of HL provided by authors in the academic literature since 2007. There is no single, commonly accepted definition of HL in the academic literature – a finding that has been reported elsewhere [5,6]. There is also no single commonly used definition of HL that appears to be more (or less) precise, clear in terms of its meaning, or useful than another. All of the most commonly used definitions of HL in the academic literature are open to multiple interpretations.

The existence of so many definitions of HL in the academic literature, and the various interpretations that are possible for the most commonly used definitions, are problematic for policymakers, practitioners and researchers. First, it is not clear which definition of HL may be best to use in any given context or the criteria by which this should be judged. Second, if policymakers' interpretations of definitions differ from those involved with the implementation and evaluation of HL-related initiatives, then these differing interpretations may lead to confusion and misunderstandings among members of these groups when communicating about HL.

Third, if policymakers act on assumptions that underlie definitions of HL, but are not fully supported by empirical research, these assumptions may lead to unintended or unwanted consequences. For example, action by policymakers on the underlying assumption inherent in Ratzan and Parker's [15] definition of HL - that is, that a positive relationship exists between an individual's "capacity to obtain, process, and understand health information and services" AND an individual making "appropriate health decisions" - may lead to the development of policies, programs, and/or practices that conflict with existing policies, programs, and practices that support potentially differing goals (e.g., wanting individuals to make "autonomous" health decisions versus health decisions that are externally defined as "appropriate"). Action on the underlying assumption may also lead to the neglect of other important factors known to influence health-related decision making (e.g., social circumstances, personal values and beliefs and the acceptability of decision-related options).

While the use of different definitions of HL, and the murkiness surrounding its meanings, may be well-tolerated, and to a large extent, encouraged by academics (i.e., through the modification of older definitions or through the development of new definitions), Hughes [14,p 46] argues that:

[F]or many specific purposes, such as doing research or enacting legislation, it makes good sense to stipulate the precise meaning that is to be attached to key words. As long as this stipulated meaning is explicitly stated, there is no risk of misunderstanding, and there is an obvious gain in clarity and precision.

Although words can always be variously interpreted, our findings pose significant challenges of those seeking to operationalize and measure HL; particularly, for the purposes of developing, implementing, and evaluating HL-related policy initiatives. Operationalization will be problematic because of the difficulty of arriving at a consensus on the interpretation of key concepts.

While we agree with McCormack et al. [24] in regards to the need to develop a shared understanding of HL for measurement-related purposes, our findings raise two important questions. First, which definition(s) of HL should be adopted for the purposes of developing, implementing, and evaluating HL-related policy initiatives – the definition(s) for which a valid and reliable empirical measure exists, the definition that is most commonly used in the academic literature, the definition(s) that best fits with a given policy context and agenda, or some combination of these and/or other criteria?

Second, who should be involved in interpreting the meaning of any given definition of HL that is adopted into policy - researchers, policymakers, and/or those who have the potential to be positively and/or negatively affected by the adoption, and interpretation of, any given definition (e.g., patients)? These are important questions that all parties must grapple with.

In regards to the measurement of HL, Pleasant and colleagues [25,p18] have proposed an agenda that would actively engage ‘the public (e.g., adult learners, patients) and policymakers’ to “help assure validity, relevance, and utility for a new comprehensive approach to measuring health literacy”. While this approach holds promise for the development, implementation, and evaluation of HL-related policy initiatives, it requires that all parties must, first, grapple with the two important questions that we raised above. Further, if the process is to be both transparent and fair, a mechanism is needed to deal openly with the power imbalances, and, potentially, conflicting interpretations, and agendas, that emerge across different interest groups (i.e., patients, researchers, health care practitioners, policymakers) throughout the entire process.

While every effort was made to ensure the accuracy of this review, some limitations exist. First, the definitions of HL were identified and extracted by the first author. To reduce the chance for bias, inclusion criterion was developed and systematically applied to every article. Following, definitions were reviewed and analyzed by the entire research team. We acknowledge that interpretations of definitions of HL, beyond those identified by the authors of this study, are possible. Second, our

search was limited to English-language only articles. Reviews, similar to that conducted by Sorensen and Brand [26], may help to gain insights into how HL is being defined, or translated, in non-English-speaking countries.

It is also important to note that the WHO [35] recently adopted a newer, and much longer, integrated definition of HL from the one shown in Tables 2 and 3. This newer definition is shown in Appendix A and did not meet the criteria for inclusion in Tables 2 and 3 (i.e., did not appear identically worded a total of five or more times in our sample), but integrates a number of components taken from other existing definitions. As shown in Appendix A, the new definition is open to varying, and potentially problematic, interpretations which are not made clear by the WHO's [35] integrated model of HL. For example, it is unclear whether or not a threshold exists for HL. The level, type, applicability, amount, acceptability, and credibility of "health information" are left open to varying interpretations. The new definition also does not specify whose "understanding" and "judgments" is valued and is still open to individualistic interpretations.

4.2 Conclusion

Prior to this review, the extent to which different definitions of HL were used in the academic literature was unknown. In this review, 250 different definitions of HL were extracted from the academic literature, and then grouped into three categories for comparative purposes. The variations among the definitions and the various interpretations that are possible for the most commonly used definitions, pose significant

challenges for the development, implementation, and evaluation of HL-related policy initiatives, as well for the measurement of HL.

4.3 Practice Implications

Careful attention is needed to the definition(s) of HL adopted in practice; the differing and, potentially problematic, ways in which definitions may be interpreted; and the way(s) in which differing interpretations may affect patient care and the delivery of HL-related policy initiatives.

Appendix: WHO (2013) definition of health literacy

<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Definition of HL and source</i>	<i>What does the definition in column 1 imply a (more) health literate person is?</i>	<i>Are there words in the definition that are vague or ambiguous?</i>	<i>What underlying assumptions are inherent in the definition?</i>	<i>Comments</i>
WHO [35,p4] “Health literacy is linked to literacy and entails people’s knowledge, motivation and competences to access, understand, appraise and apply health information in order to make judgements and take decisions in everyday life concerning health care, disease prevention and health promotion to maintain or improve quality of life during the life course.”	A (more) health literate person possesses knowledge, motivation and competences to access, understand, appraise and apply health information in order to make judgements and take decisions in everyday life concerning health care, disease prevention and health promotion to maintain or improve quality of life during the life course.	See terms in bold in column 1	Health information can be used to maintain or improve quality of life	Leaves open the level, type, applicability, source, amount, acceptability, and credibility of health information Unclear whose “understanding” and “judgements” are valued Unclear whether or not a threshold exists for HL.

Conflicts of Interest

The authors do not have any actual or potential conflicts to disclose.

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Table 1: Example of matrix used to organize definitions of HL

<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
Journal	Definitions of HL extracted from MEDLINE articles and source	Definition(s) of HL extracted from source(s) cited in MEDLINE articles and source	How do the definitions in columns 2 and 3 compare?	Comments
Pharm World Sci	“the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health” [27,p465]	“the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health.” [16,p10]	same	Identically worded

Table 2: Categories of definitions of HL identified in this review

<i>Most commonly used definitions, their source, & frequency of use in academic literature per year</i>	<i>Modified versions of commonly used definition & frequency of use in academic literature per year (selected examples)</i>	<i>“Other” definitions, their source, & frequency of use in academic literature per year (selected examples)</i>
<p>Ratzan & Parker [15,pvi]</p> <p>“the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.”</p> <p>2007 (n = 36) + 2008 (n = 34) + 2009 (n = 62) + 2010 (n = 66) + 2011 (n = 62) + 2012 (n = 49) + 2013 (n = 16) = 325 times identically worded</p>	<p>“the capacity to obtain, process, and understand health information and materials needed to make appropriate decisions regarding one’s health.” [28, pS3]</p> <p>2007 (n = 6) + 2008 (n = 8) + 2009 (n = 6) + 2010 (n = 9) + 2011 (n = 28) + 2012 (n = 28) + 2013 (n = 2) = 87 different modified versions of definition in column 1</p>	<p>“the ability of people to understand basic health information, communicate with health practitioners, and properly use health services.” [29,p377]</p> <p>“the ability to understand and interpret the meaning of health information in written, spoken or digital form and how this motivates people to embrace or disregard actions relating to health.” [30,p144]</p> <p>“the ability to understand instructions, directions, and the ability to negotiate complex health care systems.” [22,p12]</p> <p>2007 (n = 5) + 2008 (n = 4) + 2009 (n = 15) + 2010 (n = 22) + 2011 (n = 20) + 2012 (n = 29) + 2013 (n = 16) = 111 different “other” definitions (i.e., different from those in columns 1 and 2)</p>
<p>WHO[16,p10]</p> <p>“the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good <i>health</i>.”</p> <p>2007 (n = 2) + 2008 (n = 8) + 2009 (n = 14) + 2010 (n = 10) + 2011 (n = 11) + 2012 (n = 10) + 2013 (n = 5) = 60 times identically worded</p>	<p>“a patient's ability to gain access to, understand, and use information to improve health.” [21,p.e2]</p> <p>2007 (n = 0) + 2008 (n = 3) + 2009 (n = 4) + 2010 (n = 1) + 2011 (n = 4) + 2012 (n = 5) + 2013 (n = 0) = 17 different modified versions of definition in column 1</p>	
<p>AMA [17,p553]</p> <p>“a constellation of skills, including the ability to perform basic reading and numerical tasks</p>	<p>“broadly defined as the ability to read and understand essential health information in order to achieve positive health outcomes [31,p8]</p>	

<i>Most commonly used definitions, their source, & frequency of use in academic literature per year</i>	<i>Modified versions of commonly used definition & frequency of use in academic literature per year (selected examples)</i>	<i>“Other” definitions, their source, & frequency of use in academic literature per year (selected examples)</i>
<p>required to function in the health care environment.”</p> <p>2007 (n = 1) + 2008 (n = 3) + 2009 (n = 4) + 2010 (n = 6) + 2011 (n = 2) + 2012 (n = 2) + 2013 (n = 0) = 18 times identically worded</p>	<p>2007 (n=2) + 2008 (n=1) + 2009 (n=1) + 2010 (n=4) + 2011 (n=5) + 2012 (n=3) + 2013 (n = 0) = 16 different modified versions of definition in column 1</p>	
<p>Zarcadoolas et al. [18,pp196-7)</p> <p>“the wide range of skills and competencies that people develop to seek out and comprehend, evaluate, and use health information and concepts to make informed choices, reduce health risks and increase quality of life.”</p> <p>2007 (n = 1) + 2008 (n = 3) + 2009 (n = 1) + 2010 (n = 3) + 2011 (n = 2) + 2012 (n = 3) + 2013 (n = 0) = 13 times identically worded</p>	<p>“the wide range of skills and competencies people use in order to seek out, comprehend, evaluate, and use health information and concepts.” [32,p339].</p> <p>2007 (n = 0) + 2008 (n = 1) + 2009 (n = 0) + 2010 (n = 1) + 2011 (n = 3) + 2012 (n = 0) + 2013 (n = 0) = 5 different modified versions of definition in column 1</p>	
<p>Kickbusch et al. [19,p8]</p> <p>“the ability to make sound health decisions in the context of everyday life - at home, in the community, at the workplace, in the health care system, the marketplace and the political arena.”</p> <p>2007 (n = 0) + 2008 (n = 0) + 2009 (n = 5) + 2010 (n = 0) + 2011 (n = 2) + 2012 (n = 3) + 2013 (n = 1) = 11 times identically worded</p>	<p>“the ability to make sound health decisions in the context of everyday life.” [33,p1800]</p> <p>2007 (n = 0) + 2008 (n = 0) + 2009 (n = 0) + 2010 (n = 0) + 2011 (n = 2) + 2012 (n = 0) + 2013 (n = 0) = 2 different modified versions of definition in column 1</p>	

<i>Most commonly used definitions, their source, & frequency of use in academic literature per year</i>	<i>Modified versions of commonly used definition & frequency of use in academic literature per year (selected examples)</i>	<i>“Other” definitions, their source, & frequency of use in academic literature per year (selected examples)</i>
<p>Rootman & Gordon-El-Bihbety [20,p11]</p> <p>“the ability to access, understand, evaluate and communicate information as a way to promote, maintain and improve health in a variety of settings across the lifecourse”</p> <p>2007 (n = 0) + 2008 (n = 0) + 2009 (n = 1) + 2010 (n = 2) + 2011 (n = 1) + 2012 (n = 3) + 2013 (n = 0) = 7 times identically worded</p>	<p>“the ability of individuals to obtain, understand and act upon health information and to make appropriate health decisions, with the ultimate goal being the maintenance of health or the management of disease in a variety of settings across the life-course.” [34,p451]</p> <p>2007 (n = 0) + 2008 (n = 1) + 2009 (n = 1) + 2010 (n = 1) + 2011 (n = 2) + 2012 (n = 1) + 2013 (n = 0) = 6 different modified versions of definition in column 1</p>	

Table 3: Summary of findings from the critical analysis of the most commonly used definitions of HL identified in this review

<i>1</i> <i>Definition of HL and source</i>	<i>2</i> <i>What does the definition in column 1 imply a (more) health literate person is?</i>	<i>3</i> <i>Are there words in the definition that are vague or ambiguous?</i>	<i>4</i> <i>What underlying assumptions are inherent in the definition?</i>	<i>5</i> <i>Comments</i>
Ratzan & Parker [15,pvi] “the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions. ”	A (more) health literate individual has a (greater) degree of capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.	See terms in bold in column 1	HL is needed to make “appropriate” health decisions	Implied onus on the individual to achieve HL Leaves open the level, type, applicability, source, amount, acceptability, and credibility of the basic health information and services “needed”. Unclear: (1) whose “understanding” or “need” is valued, or (2) who determines what “appropriate” decisions are, or what criteria that determination is based on. Does not take into account contextual factors that may limit/prevent “obtaining” Focus on “appropriate” decisions make HL a particularly normative concept.
WHO [16,p. 10] “the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use	A (more) health literate individual possesses (more of the) the cognitive and social skills	See terms in bold in column 1 Relationship of HL to health is conditional on possessing cognitive and	Health can be promoted or maintained with health information	Implied onus on the individual to achieve HL Unclear whether or not a threshold exists for HL

<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Definition of HL and source</i>	<i>What does the definition in column 1 imply a (more) health literate person is?</i>	<i>Are there words in the definition that are vague or ambiguous?</i>	<i>What underlying assumptions are inherent in the definition?</i>	<i>Comments</i>
information in ways which promote and maintain good health. "	which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health	social skills and the motivation and ability to access, understand, and use information. Cognitive and social skills seem necessary but together are they sufficient to achieve HL?		<p>Different from other definitions because it includes a motivational component</p> <p>Leaves open the level, type, applicability, source, amount, acceptability, and credibility of "information".</p> <p>Does not specify whose "understanding" is valued</p> <p>Does not take into account contextual factors that may limit/prevent gaining access to, understanding or using</p>
AMA [17,p553] "a constellation of skills , including the ability to perform basic reading and numerical tasks required to function in the health care environment. "	A (more) health literate person possesses (more of) a constellation of skills, including the ability to perform basic reading and numerical tasks required to function in the health care environment.	<p>See terms in bold in column 1</p> <p>Unclear whether or not the identified skills are viewed as necessary or sufficient to achieve HL</p>	A relationship exists between the possession of a set of skills and "functioning" in the health care environment	<p>Does not take into account contextual factors that may limit/prevent functioning</p> <p>Unclear whether or not a threshold exists for adequate HL or functioning in the health care environment</p>

<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Definition of HL and source</i>	<i>What does the definition in column 1 imply a (more) health literate person is?</i>	<i>Are there words in the definition that are vague or ambiguous?</i>	<i>What underlying assumptions are inherent in the definition?</i>	<i>Comments</i>
Zarcadoolas et al. [18,pp196-7] “the wide range of skills and competencies that people develop to seek out and comprehend, evaluate, and use health information and concepts to make informed choices, reduce health risks and increase quality of life. ”	A (more) health literate person possesses the wide range of skills and competencies that people develop to seek out and comprehend, evaluate, and use health information and concepts to make informed choices, reduce health risks and increase quality of life.	See terms in bold in column 1 Unclear whether or not the identified skills are viewed as necessary or sufficient to achieve HL	Health information and concepts can be used to reduce health risks and increase quality of life	Implied onus on “people” to achieve HL Does not specify whether or not a threshold exists for HL Leaves open the source, level, credibility, amount, acceptability, and applicability of health information and concepts. Does not specify whose “comprehension” is valued Does not take into account contextual factors that may limit/prevent seeking, comprehending, evaluating, using, reducing health risks, or quality of life
Kickbusch et al. [19,p8] Ability to ‘make sound health decisions in the context of everyday life at home, in the community, at the workplace, in the health care system, the marketplace and the political arena.’”	A (more) health literate person is able to make sound health decisions in the context of everyday life at home, in the community, at the workplace, in the health care	See terms in bold in column 1 HL is seen as an “ability” Is this the same as a capacity or skill?	Equates HL with the ability to make sound decisions.	Does not specify who determines what “sound health decisions” are. Different from other definitions because HL is relevant to multiple contexts Does not take into account contextual factors that may limit/prevent “sound health decisions”

<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Definition of HL and source</i>	<i>What does the definition in column 1 imply a (more) health literate person is?</i>	<i>Are there words in the definition that are vague or ambiguous?</i>	<i>What underlying assumptions are inherent in the definition?</i>	<i>Comments</i>
	system, the marketplace and the political arena.			
Rootman and Gordon-El-Bihbety [20,p11] “the ability to access, understand, evaluate and communicate information as a way to promote, maintain and improve health in a variety of settings across the lifecourse”	A (more) health literate person possesses the ability to access, understand, evaluate and communicate information as a way to promote, maintain and improve health in a variety of settings across the lifecourse	See terms in bold in column 1 Unclear whether or not the identified skills are viewed as necessary or sufficient conditions to achieve HL.	Information can be used in ways to promote, maintain and improve health.	Leaves open the type, source, level, credibility, amount, acceptability, and applicability of information Does not specify whose “understanding” is valued Different from other definitions because it specifies both context and timeframe Does not take into account contextual factors that may limit/prevent accessing, understanding, evaluation, communication, promotion, maintaining, or improving health

Chapter 3: Empirical Relationships Between Health literacy and Treatment Decision making: A Scoping Review of the Literature

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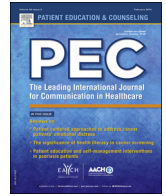
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Preface

The study presented in Chapter 3 has been published by *Patient Education and Counseling*. This study challenges existing notions about the relationships that exist between health literacy and treatment decision making and has important implications for policy initiatives seeking to involve patients in treatment decision making. The findings show that the relationships between health literacy and treatment decision making are not clear due to important gaps and knowledge and multiple methodological problems. These gaps and problems are priority areas for future research.

In preparation for this study, I consulted with Maureen Rice at McMaster University. She provided me assistance with identifying the most appropriate databases and search terms to use. I carried out all of the database searches, downloaded all of the records returned, developed the relevance screening criteria used to identify studies for inclusion, applied all of the relevance screening to articles, developed the data charting form, extracted relevant data from all studies, organized, analyzed, and interpreted the data, and wrote multiple iterations of the manuscript. Dr. Charles, Dr. Gafni, and Dr. Entwistle helped with the pilot testing of the relevance screening criteria. Dr. Charles assisted with the pilot testing of the data charting form. Dr. Malcolm Weir acted as a second reviewer during all levels of relevance screening. Dr. Charles, Dr. Gafni, and Dr. Entwistle provided feedback on my analysis as well as feedback on multiple iterations of the manuscript.



Review

Empirical relationships between health literacy and treatment decision making: A scoping review of the literature



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ABSTRACT

Objectives: This study asked: What is known from the existing literature about the empirical relationships between health literacy (HL) and the three stages of the treatment decision making (TDM) process: information exchange, deliberation, and deciding on the treatment to implement?

Methods: A scoping review of the literature was conducted. Four databases were searched and a total of 2772 records were returned. After de-duplication and three levels of relevance screening, 41 primary studies were included.

Results: Relationships between HL and information exchange were studied more often than relationships between HL and deliberation and deciding on the treatment to implement. Across the 41 studies, there was little overlap in terms the measure(s) of HL adopted, the aspect of TDM considered, and the characteristics of the study populations – making comparisons of the findings difficult. Multiple knowledge gaps and measurement-related problems were identified; including, the possibility that the process of TDM influences HL.

Conclusion: The importance of HL to the three stages of TDM is unclear because of the knowledge gaps and measurement-related problems that exist.

Practice implications: There are many uncertainties about how TDM, or the design and use of patient decision aids, should respond to patients with different levels of HL.

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1. Background

Internationally, there has been a growing trend toward the implementation and, in some cases legislation, of shared decision making (SDM) in the clinical encounter [1,2]. Although the term SDM has been variously defined, one of the key features of SDM is that both physicians and patients “take steps to participate in the process of treatment decision-making” [3^(p686)].

Related to the movement to implement SDM, is a growing international movement to promote the implementation of patient decisions aids (PDAs) in clinical practice [2]. PDAs have been defined by the International Patient Decision Aid Standards Collaboration [4^(para1)] as, “tools designed to help people participate in decision making about health care options. They provide information on the options and help patients clarify and communicate the personal value they associate with different features of the options”.

Relevant to the shift to implement SDM and PDAs in clinical practice, is the notion that health literacy (HL) is important to treatment decision making (TDM). Claims to support this notion can be found in statements made in the academic literature; for example: “health literacy is *required* for patients to *effectively use decision aids*” [5^(p2)]; “health literacy is a *prerequisite* for *informed health care decision making*” [6^(p1)]; and “[I]mproving health literacy has the *potential to promote*”, among other things, “*more informed decision making*” [7^(p200)]. These statements generally imply that HL influences TDM.

Reflecting and/or reinforcing the notion that HL is important to TDM are provisions found within the 2010 U.S. Patient Protection and Affordable Care Act (ACA), Section 936, which is titled “Program to Facilitate Shared Decisionmaking”, includes provisions supporting the development, updating, and production of PDAs that “present up-to-date clinical evidence about the risks and benefits of treatment options” in a manner that, among other things, “reflects the varying needs of consumers and diverse levels of *health literacy*” [8^(p1090)]. Implied in these provisions is the notion that people with different levels of HL have different needs that should be respected with regard to the way that information about treatment options and their risks and benefits are presented in PDAs. That is, a particular PDA developed for patients with a high level of HL may not meet the needs of patients with a low level of HL.

Ethical arguments for enabling people to participate in decision making about their treatment are now widely accepted. However, many uncertainties remain about how this is best done, in part because of uncertainties about relationships between HL and TDM [9,10]. Policy initiatives, such as the 2010 U.S. ACA, make it particularly important to attend to these uncertainties. In this study we sought to answer: *What is known from the existing literature about the empirical relationship(s) between HL and TDM?*

2. Methods

2.1. Research design

A scoping review of the literature was undertaken using the approach described by Arksey and O'Malley [11]. Scoping reviews allow researchers to: (1) examine, or map, the extent, range, and nature of research activity in a topic area of interest; (2) “identify gaps in the existing literature”; and (3) “determine the value of undertaking a full systematic review” [11^(p.21)]. In the adopted approach, five stages are outlined. A description of how these five stages were applied in this review follows.

2.2. Identification of the scoping review question (Stage 1)

To allow for a broad and inclusive approach to the topic of interest, the Charles et al. [3] TDM framework was also adopted in this study. In this framework, different approaches to TDM (i.e., informed, shared, paternalistic) are described as well as three analytic stages that are common to each of the different approaches (i.e., information exchange, deliberation, deciding on the treatment to implement). To reflect this conceptualization of TDM, the research question was adjusted to: *What is known from the existing literature about the empirical relationship(s) between HL and the three stages of the TDM process?*

2.3. Identification of relevant studies (Stage 2)

To identify relevant studies, a literature search strategy for the four electronic databases listed in Table 1 was developed in consultation with a specialist librarian. Terms relating to health literacy and to treatment decision making (including physician–patient communication) were identified for each database. The search terms and combinations used in each database can be found in Online Appendices A–D.

As shown in Fig. 1, a total of 2772 records were retrieved from the four databases. A search of the reference lists of all review papers ($n=83$) did not lead to the identification of any new records. After de-duplication, 2023 records remained and were uploaded into Distiller SR © for relevance screening.

2.4. Study selection (Stage 3)

Two levels of relevance screening criteria were developed, agreed upon, and pre-tested on a small sub-set of records by all of the authors. The first level of relevance screening (RS1) criterion was applied to the title and abstracts of all remaining records by LMW and MW. Records remaining after RS1 were read in full by LMW and MW to determine whether or not they met the second level (RS2) of inclusion criterion. Following RS2,

Table 1
Databases searched for the scoping review.

Database type	Database	Temporal period covered (Start date reflects the year in which each database was established. End date is the date in which the search was limited to)
Academic	Medline (Ovid)	1946–31/12/2013
Academic	Embase	1980–31/12/2013
Academic	CINAHL	1982–31/12/2013
Academic	Eric	1966–31/12/2013

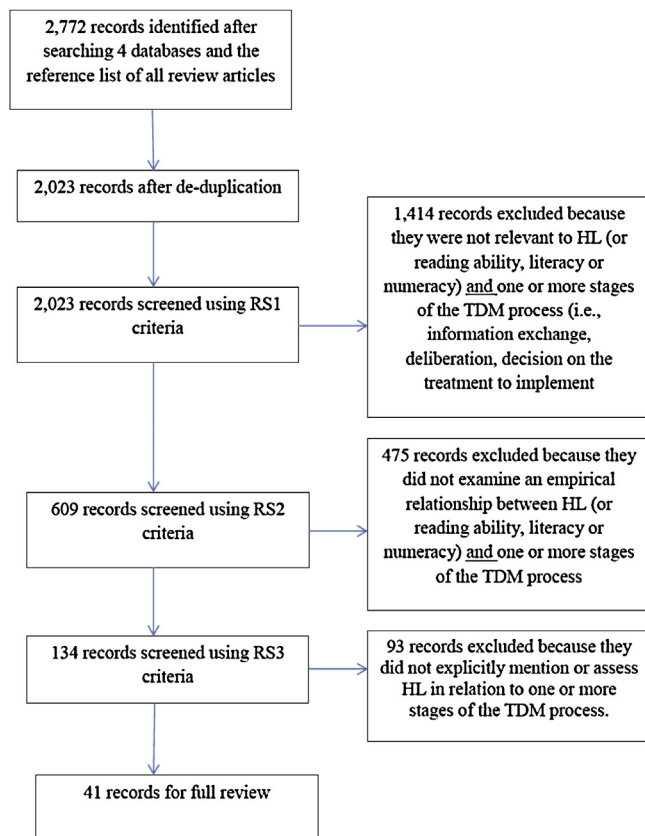


Fig. 1. Flow chart illustrating the total number of records retrieved from four databases and the relevance screening process.

a decision was made to exclude studies that did not explicitly mention the term HL, or assess HL (i.e., those that examined vision-related reading ability, literacy, or numeracy). This decision was made given: (1) that HL was one of the key terms in our scoping review question, and (2) the limited time and resources available to conduct this review. The exclusion of these studies was done through the application of a third level of relevance screening criterion (RS3). The entire relevance screening process is depicted in Fig. 1. Any conflicts arising during this process were discussed and resolved by the LMW and MW and/or the research team.

2.5. Charting the data (Stage 4)

A data charting form (DCF) was developed and pre-tested independently by LMW and CAC on a small subset of studies. After pre-testing, LMW applied the DCF to the remainder of the studies. The following information was charted, if provided: author(s), publication date, location; intervention type, and comparator; characteristics of the study populations; study aims; methodology; outcome measures; and results relevant for answering the scoping review question. Any definition(s) of HL adopted, the instrument(s) used to assess HL, the type(s) of TDM approaches examined, and the stage(s) of TDM examined were also charted.

2.6. Collating, summarizing, and reporting the results (Stage 5)

In the sections that follow, a narrative account is provided of the temporal and geographical distribution of the 41 studies included in this review; the research designs and study populations used; and the definitions and measures of HL adopted by researchers.

The empirical relationships relevant for answering the research question are then reported and thematically organized according to their relevance to the three stages of TDM. Quality appraisal of studies is not an integral part of the adopted scoping review method [11]; however, the limitations in the methods used, and the gaps in the existing literature, are noted as well as their implications for research, policy, and practice.

3. Results

3.1. Temporal and geographical distribution of the 41 studies

Forty of the 41 studies included in the review were published after the year 2001, with the majority ($n = 31$) being published in the years between 2009 and 2013. Thirty-four studies were conducted in the U.S. Two studies were conducted in Australia. Only one study was conducted in each of the following countries: U.K., Germany, Japan, Taiwan, and the Netherlands.

3.2. Research designs and study populations

Cross-sectional correlational studies ($n = 18$) were the most prevalent, followed by experimental or quasi-experimental ($n = 10$), qualitative ($n = 9$), and mixed-methods ($n = 4$) studies. Across studies, the number, socio-demographic characteristics, and health status, of the patients recruited varied. Patients diagnosed with cancer, or at risk for developing cancer, were the patient group most commonly focused on. Patients who were White, female, English-speaking, 50 years of age and older, and more health literate (as deemed by the authors) featured more often in study samples than their non-White, male, non-English-speaking, younger and less health literate counterparts.

3.3. Definitions and measures of HL

Twenty-one studies provided one or more definitions of HL. These definitions are listed in column three of Tables 2–4. Ratzan and Parker's [12] definition of HL appeared in 14 studies. Ratzan and Parker [12^(pxi)] define HL as “the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions”. The remaining studies provided different definitions of HL. Two studies provided multiple definitions of HL.

The measures of HL adopted in studies are listed in column four of Tables 2–4. The Rapid Estimate of Adult Literacy in Medicine (REALM), or a shortened, modified, or translated version of the REALM, was the most commonly used in studies. This “is a screening instrument to assess an adult patient's ability to read [or pronounce] common medical words and lay terms for body parts and illnesses” [13^(para1)].

Three studies used the Test of Functional HL in Adults (or TOFHLA), eight used the shortened version (or S-TOFHLA), and five used a Spanish version. The TOFHLA is a timed test of reading comprehension of passages taken from “instructions for preparation for an upper gastrointestinal series, the patient rights and responsibilities section of a Medicaid application form, and a standard hospital consent form” [21^(p538)]. Six studies used measures of HL other than the REALM or TOFHLA (or S-TOFHLA) [16,18,28,30–32]. Five studies used more than one measure of HL [16,18,22,28,30].

A comparison of the definitions and measures of HL listed in columns 3 and 4 of Tables 2–4 reveals the following. First, some of the constructs assessed by measures of HL were not fully, or even partially (in some cases), congruent with the underlying components of definitions of HL provided by authors in their studies. To illustrate, Ratzan and Parker's [12^(pxi)] definition of HL – “the

Table 2
Empirical studies included in the scoping review that have relevance to the information exchange stage of TDM.

Reference	Characteristics and location of study population	Definition(s) of HL provided by authors	Instrument(s) used by researchers to assess HL	Empirical relationship(s) examined or reported on in study	Finding(s) (*unique or unexpected finding)
[34]	N= 63 cancer patients Mean age: 49.5 years United States (Southeastern city)	None provided	REALM	Patients' REALM scores and patients' desire for information (unspecified type)	No relationship observed
[22]	N= 138 patients with various types of cancer Mean age: 52.1 (± 11.9) years United States (Virginia)	Ratzan and Parker's [12 ^(pxi)] definition	REALM and S-TOFHLA	Patients' REALM and S-TOFHLA scores and patients' self-reported information needs regarding disease, diagnostic tests, treatment, self-care, emotional and psychological needs, and other tangible information needs	No relationship observed
[45]	N= 163 breast cancer patients Mean age: 58.8 years United States (North Carolina)	Ratzan and Parker's [12 ^(pxi)] definition	REALM –	Patients' REALM scores and patients' desire for information for additional information about a recurrence risk test	No relationship observed
[18]	N= 73 patients with chronic, acute, or mental health conditions Age range: 55–64 years Australia	Ratzan and Parker's [12 ^(pxi)] definition Added the following: "...some experts argue that HL means more than the ability to read information; it extends to the ability to interact with a health professional and exert greater control over everyday situations (p. 1806)	TOFHLA & NVS	Patients' TOFHLA and NVS scores and patients' health information seeking habits	Patients wanted information when a health decision was being made regardless of their TOFHLA score
[49]	N= 8 caregivers to patients with ALS Mean age: 56 years Australia	None provided	Not assessed quantitatively	HL and caregivers' participation in decision-making for ALS multidisciplinary care	*Caregivers provided HL support to patients by "sourcing, collation, and provision of information about ALS and associated health and community services to support and develop the decision-making capacity of the patient" (p. 174)
[42]	N= 321 cardiology patients Mean age: 64 years United Kingdom	Provided multiple definitions but chose to adopt Ratzan and Parker's definition in their study because it fit best with the REALM	REALM –	Patients' REALM scores and patients' perceptions of the doctor-patient relationship and information giving	Quotes provided from 2 patients who scored low on the REALM indicated that they didn't want to know "too much" or "preferred not to know"
[30]	N= 134 patients with Type II diabetes Mean age: 65.0 years Japan	"...Nutbeam proposed a model of HL that includes three levels: functional literacy, the basic level of reading and writing skills that allow a person to function effectively in everyday situations; communicative literacy, advanced skills that allow a person to extract information, derive meaning from different forms of communication and apply new information to changing circumstances and critical literacy, more advanced skills to critically analyze information and use information to exert greater control over life events and situations" (p. 518)	Functional, Communicative, and Critical HL	Patients' scores on the functional, communicative, and critical HL scales and the: (1) number of questions patients asked their physicians to seek information, and (2) the type of information patients' provided during information exchange	Patients with higher communicative HL scores asked more questions than patients with higher functional and critical HL scores (OR's 2.25, CI: 1.76–2.88 vs. 0.96, CI: 0.75–1.24 and 1.24, CI: 0.71–2.17 respectively) Patients with higher critical HL provided more psychosocial information than patients with higher functional and communicative HL scores (OR's 2.26, CI: 1.06–4.82 vs. 0.89, CI: 0.56–1.40 and 1.15, CI: 0.61–2.15 respectively)
[43]	N= 275 urban primary care patients diagnosed with hypertension Mean age: 61.2 years United States	Ratzan and Parker's [12 ^(pxi)] definition	REALM	Patients' scores on the REALM and patient medical question asking across patients and physicians that received different types of communication skills training: (1) minimal patient/minimal physician; (2) intensive patient/minimal physician; (3) minimal patient/intensive physician; (4) intensive patient/intensive physician	No statistically significant differences between patients with low and adequate literacy in terms of patient medical question asking in the following intervention groups: minimal patient/minimal physician; intensive patient/minimal physician; and minimal patient/intensive physician In the intensive patient/intensive physician group, patients with adequate HL asked, on average, a greater number of medical questions than those with low HL (6.42 vs 3.85, $p=0.002$)

Table 2 (Continued)

Reference	Characteristics and location of study population	Definition(s) of HL provided by authors	Instrument(s) used by researchers to assess HL	Empirical relationship(s) examined or reported on in study	Finding(s) (*unique or unexpected finding)
30	N=134 patients with Type II diabetes Mean age: 65.0 years Japan	"...Nutbeam proposed a model of HL that includes three levels: functional literacy, the basic level of reading and writing skills that allow a person to function effectively in everyday situations; communicative literacy, advanced skills that allow a person to extract information, derive meaning from different forms of communication and apply new information to changing circumstances and critical literacy, more advanced skills to critically analyze information and use information to exert greater control over life events and situations" (p. 518)	Functional, Communicative, and Critical HL	Patients' scores on the functional, communicative, and critical HL scale and the: (1) types of questions asked by physicians (closed vs open-ended); (2) the information given by physicians; and (3) the counseling/direction used by physicians	Physicians "used more closed-ended questions and provided more information to patients with higher functional HL" (p. 521) Physicians used less counseling and direction, and fewer closed-ended questions with patients with higher critical HL
[23]	N=75 diabetic patients Mean age: 64 years United States (California)	Ratzan and Parker's [12 ^(pxi)] definition	S-TOFHLA	Patients' scores on the S-TOFHLA and primary care physicians' use of unclarified clinical jargon	Physicians used unclarified medical jargon when speaking with patients with limited HL approximately every 5 min and did so most frequently when making recommendations, providing health education, and delivery test results to patients Patients knowledge scores correlated with their REALM scores (Pearson correlation $r=0.65$, $p=0.0001$)
[48]	N=30 cancer patients Mean age: 67 years United States (Chicago, IL)	None provided	REALM	Patients' score on the REALM and patients' scores on the prostate cancer knowledge	Positive relationship between patients' scores on the S-TOFHLA and patients' knowledge about home therapy (Pearson correlation $r=0.64$, $p\leq 0.01$)
[24]	N=106 patients from a community clinic Mean age: 52.58 (± 5.35) years United States	Ratzan and Parker's [12 ^(pxi)] definition	S-TOFHLA	Patients' scores on the S-TOFHLA and patients' knowledge about hormone therapy	Average S-TOFHLA score for the group indicated marginal levels of HL. As a group, patients' lacked "knowledge about their condition both before and after the physician encounter" and experienced "only minor improvement in knowledge about these conditions despite extensive explanations using pelvic models and/or interpreters" (p. 93)
[25]	N=25 female, Spanish-speaking patients with pelvic floor disorders Mean age: 55.5 years United States (Los Angeles, CA)	None provided	S-TOFHLA –	Patients' score on the S-TOFHLA and patients' knowledge of pelvic floor disorders before and after a visit with their physician	Patients with higher scores on the TOFHLA had "a good understanding of their treatment plan" but an "incomplete understanding of their diagnosis" after a visit with their physician (p. 138)
[19]	N=20 patients with pelvic floor disorders Mean age: 60.5 years United States (Los Angeles, CA)	"The ability to perform basic reading and numerical tasks required to function in the health care environment" (p. 137)	TOFHLA	Patients' score on the TOFHLA and patients' understanding of diagnosis and treatment plan after a visit with their physician	Rates of comprehension among patients with limited reading comprehension and numeracy ability were "very low and never exceeded 40% regardless of the method of assessment or presence and nature of context" (p. S90)
[23]	N=75 diabetic patients Mean age: 64 years United States (California)	Ratzan and Parker's [12 ^(pxi)] definition	S-TOFHLA	Patients' score on the S-TOFHLA and patients' comprehension of 19 diabetes-related jargon terms used by their physicians in clinical encounters with patients	Comprehension of terms in 3 functional domains was significantly correlated with REALM scores: urinary (Spearman's correlation $r=0.55$, $p<0.01$), bowel (Spearman's correlation $r=0.54$, $p<0.01$), and sexual (Spearman's correlation $r=0.56$, $p<0.01$)
[35]	N=109 patients from a Urology Clinic and Radiation Oncology Center Mean age: 55.2 years United States (Atlanta, GA)	Ratzan and Parker's [12 ^(pxi)] definition	REALM	Patients' score on the REALM and patients' comprehension of common prostate health terms	

[17]	N= 144 patients receiving a total hip or knee replacement Age: 72% over the age of 50 Taiwan (Southern)	None provided	REALM	Influence of patient-perceived empathy on the relationship between patients' REALM score and patients' understanding of preoperative information	*Patient-perceived physician empathy had a moderating effect on the relationship between patients' REALM scores and patients' understanding of perioperative information
[50]	N= 12 patients with acute myeloid leukemia Age range: 21–76 years Germany	None provided	Not assessed quantitatively	The cognitive constructions that patients with AML make regarding the nature of their disease, its source; and its treatment	"Patients' vague subjective conceptions about the personalized etiology of AML resulted not only from HL deficits but also from their avoiding medical information to protect themselves from negative emotions" (p. 5)
[51]	N= 50 women with severe maternal morbidity Age range: not reported The Netherlands	Ratzan and Parker's [12 ^(pxi)] definition	Not assessed quantitatively	Patients, husbands, and friends perceptions about the recognition of complaints by health care providers, and their communication with them	Reported under the heading "HL": "...even highly education women from the smaller migrant groups who presented themselves as critical health consumers, showed <i>low HL</i> skills. They did understand basic health information, but lacked the appropriate communication strategies to interact adequately with caregivers, and vice versa as regard those same caregivers. This was one of the most important findings our study" (p. 49)
[9]	N= 58 breast cancer patients (only 58 had HL assessed) Median age: 59 years United States	Ratzan and Parker's [12 ^(pxi)] definition	REALM	Patients' score on the REALM and patients' ability to estimate breast cancer recurrence risk for themselves and for others' – both estimates were based on hypothetical information	Patients with lower scores on the REALM "gave more variable interpretations of recurrence risks described in words" (p. 160) When interpreting risks described as being their own, "patients with lower scores on the REALM "used higher numbers to describe "low chance," but this difference did not reach statistical significance...patients with lower scores on the REALM had greater variability in the numbers they used to interpret "low chance" of recurrence than women with higher health literacy ($p=0.02$)" (p. 160)
[33]	N= 120 patients with a family or personal history of breast or ovarian cancer Age range: 20–69 years United States	Ratzan and Parker's [12 ^(pxi)] definition	REALM	Patients' REALM scores and patients' understanding of "four hypothetical representations of breast cancer risk" (p. 94)	No relationship observed
[14]	N= 133, Breast cancer patients – but only 58 had HL assessed Age: Not reported United States (North Carolina)	None provided	REALM-R	Patients' scores on the REALM-R and patients' objective and perceived understanding of breast cancer recurrence risk after viewing 6 different "vignettes that presented hypothetical recurrence risk test results" in different formats (p. 553)	Patients' scores on the REALM-R were not associated with patients' ability to correctly identify whether a result was low, intermediate or high recurrence risk
[15]	N= 408 parents of children scheduled for elective surgery Mean age: 36 years United States	None provided	REALM	Caregivers' scores on the REALM and caregiver's (1) verbatim understanding (i.e., risks and benefits of the absolute risk and benefit frequencies, and (2) gist understanding (i.e., the "essential meaning about the differences between the risks and benefits of two drugs") (p. 719)	Lower scores on the REALM-R were associated with lower perceived understanding of test results overall ($p=0.01$)
[36]	N= 131 low-income adults Mean age: 42.9 years United States (Indiana)	None provided	REALM	Patients' scores on the REALM and patients' satisfaction with health care providers' communication	Among parents with both low and high scores on the REALM: (1) verbatim understanding was greatest when information was presented in tables; and (2) gist understanding was greatest when information was presented in tables or pictographs
					Inverse relationship observed

Table 2 (Continued)

Reference	Characteristics and location of study population	Definition(s) of HL provided by authors	Instrument(s) used by researchers to assess HL	Empirical relationship(s) examined or reported on in study	Finding(s) (*unique or unexpected finding)
[46]	N=84 cardiac patients Age range: 24–80 years United States (Atlanta, GA)	Ratzan and Parker's [12 ^(pxi)] definition	REALM	Patients' scores on the REALM and patients' ratings of the quality of physician-patient communication during hospitalization (i.e., general clarity, responsiveness to patient concerns, explanations of care, explanations of condition and prognosis)	Patients' who were categorized as inadequate on the REALM gave significantly worse ratings in regards to physicians' general clarity, responsiveness to patient concerns, and explanations of care No relationship observed between patients' scores on REALM and patients' ratings of physicians' explanations of condition and prognosis
[26]	N=408 patients with Type II diabetes Mean age: 54 years and older United States (San Francisco, CA)	"FHL is a measure of a patient's ability to perform basic reading and numerical tasks required to function in the health care environment" (p. 315)	S-TOFHLA	Patients' scores on the S-TOFHLA and patients' ratings of quality of physician-patient communication	In adjusted analyses, patients with low scores on the S-TOFHLA (compared to patients with high scores), "were more likely to report worse communication in the domains of general clarity (adjusted odds ratio [AOR] 6.29, $p < 0.01$), explanation of condition (AOR 4.85, $p = 0.03$), and explanation of processes of care (AOR 2.70, $p = 0.03$)." (p. 315)
[16]	N=90 patients with AIDS Mean age: 40.8 (± 8.77) years United States (California)	"Functional HL refers to individuals' abilities to read and comprehend prescription bottles, appointment slips, and other materials that ensure their successful functioning in the patient role." (p. 284)	REALM General HL measure to assess patients' HIV illness and treatment knowledge and misconceptions Investigator – designed measure of patients' understanding of prescription labels	Patients' scores on the General HL and patients' ratings of overall quality of their providers' communication skills Patients' understanding of prescription labels and patients' ratings of overall quality of their providers' communication skills	The "quality of provider communications were significantly associated with scores on the knowledge/misconception measure ($r = 0.17$, $p \leq 0.10$), recognition ($r = 0.28$, $p \leq 0.01$), and understanding of HIV terms ($r = 0.28$, $p \leq 0.01$). The relationship between understanding of prescription instructions and overall quality of provider communications was not significant." (p. 294)
[47]	N=399 patients with chronic kidney disease Age range: 46–67 years United States	None provided	REALM	Patients' scores on the REALM and patient satisfaction with provider communication	No relationship observed
[44]	N=31 diabetic African American patients United States (southeastern, large urban public hospital)	Ratzan and Parker's [12 ^(pxi)] definition	REALM	Patients' scores on the REALM and the prototypes of control that were adopted during physician-patient interactions	Mutuality was the most common prototype during physician-patient interactions across all levels of REALM scores Patients with lower REALM scores tended to have more paternalistic physician-patient interactions than patients with higher REALM scores Consumerism prototype observed more frequently among patients with marginal or adequate REALM scores

Table 3

Empirical studies included in the scoping review that have relevance to the deliberation stage of TDM.

Reference	Characteristics and location of study population	Definition(s) of HL provided by authors	Instrument(s) used by researchers to assess HL	Empirical relationship(s) examined or reported on in study	Finding(s) (*unique or unexpected finding)
[20]	N=175 asthma patients United States (New York City)	"HL refers to the ability to read, understand, and communicate health information (1)." (p. 41)	TOFHLA	Patients' TOFHLA scores and patients' desire to participate in making decisions about their treatment	In adjusted analysis, patients with marginal/inadequate scores on the TOFHLA were 1.16 times more likely ($p=0.01$) to report that they did not want to participate in making treatment decisions (compared to patients with adequate scores on the TOFHLA)
[27]	N=823 caregivers to children presenting for an acute care visit to a pediatric clinic United States (New York)	None provided	S-TOFHLA	Caregivers' scores on the S-TOFHLA and caregivers' perceptions and attitudes toward participatory decision making with the provider	Caregivers who scored low on the S-TOFHLA reported not feeling "like a partner in their child's care", and strongly preferred to rely on their doctor's knowledge and leave decisions up to the doctor" (p. 121)
[45]	N=163 patients previously diagnosed with stage I or II primary breast cancer United States (North Carolina)	Ratzan and Parker's [12 ^(pxi)] definition	REALM	Patients' REALM scores and patients' preferences for active participation in decision making	No relationship observed
[43]	N=275 urban primary care patients diagnosed with hypertension Mean age: 61.2 years United States	Ratzan and Parker's [12 ^(pxi)] definition	REALM	Patients' scores on the REALM and patients' desire to participate in decision making	No statistically significant difference in patients' desire to participate in decision making between patients with low and adequate HL
[28]	N=100 Patients with some form of cardiovascular disease United States (Virginia)	None provided	S-TOFHLA and one-item FHL screen questions	Patients' scores on the S-TOFHLA and patients' decision making style	Compared to patients with inadequate scores on the S-TOFHLA, patients' with adequate and marginal scores were more likely to prefer an active decision making style (i.e., making the final selection with or without input from the doctor or sharing the decision with the doctor) than patients' who were categorized as inadequate on the S-TOFHLA (OR's 3.29, CI: 1.12–9.69 and 4.22, CI: 1.06–16.9 respectively)
[52]	N=51 diabetic patients United States	"HL includes access to health information and the ability to process such information in a meaningful way." (p. 1136)	Not assessed quantitatively	Patients' ability to make informed decisions	Reported under the heading "HL": "Some participants felt unprepared to make informed decisions about their health because of inadequate medical knowledge. Others reported being unable to comprehend medical jargon and feeling too disempowered to ask clarifying questions" (p. 1136)
[18]	N=73 Patients with chronic, acute, or mental health conditions Australia	Ratzan and Parker's [12 ^(pxi)] definition Added the following: "...some experts argue that HL means more than the ability to read information; it extends to the ability to interact with a health professional and exert greater control over everyday situations (p. 1806)	TOFHLA & NVS	Patients' "recent or past experiences of involvement, views on the advantages and disadvantages of being involved" (p. 1807)	A quote was provided from one patient who had a high score on the TOFHLA but was not interested in knowing the pros or cons or having a conference to think about a decision
[24]	N=106 patients recruited from a community clinic United States	Ratzan and Parker's [12 ^(pxi)] definition	S-TOFHLA	Patients' score on the S-TOFHLA and patients' decision self-efficacy (i.e., self-confidence in making an informed choice)	Positive correlation between patients' scores on the S-TOFHLA and patients' decision self-efficacy (Pearson's $r=0.69$, $p\leq 0.01$)
[46]	N=84 patients with suspected ACS and evidence of myocardial ischemia United States (Atlanta, GA)	Ratzan and Parker's [12 ^(pxi)] definition	REALM	Patients' scores on the REALM and patients' responses to the following question: Did the doctors try to involve you or include you in decisions about treatment?	No relationship observed

Table 3 (Continued)

Reference	Characteristics and location of study population	Definition(s) of HL provided by authors	Instrument(s) used by researchers to assess HL	Empirical relationship(s) examined or reported on in study	Finding(s) (*unique or unexpected finding)
[37]	N = 18 physicians N = 73 standardized patients United States (New Orleans, LA)	Ratzan and Parker's [12 ^(p.93)] definition	REALM	Standardized patients' perceived participation in decision making	All standardized patients had low scores on the REALM and "rated doctor facilitation and information exchange as good or better but rated poorly their own participation in decision-making" (p. 128)
[25]	N = 25 female patients with pelvic floor disorders United States (Los Angeles, CA)	None provided	S-TOFHLA	Patients' decision making	Patients' mean scores on the S-TOFHLA were "adequate" – "... patients' placed complete trust in the physician and ultimately relied on the physician to make decisions for them" (p. 93)

degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions" – was matched most commonly with the REALM which assesses a person's ability to pronounce medical terms.

Second, some measures of HL focused on a single dimension (e.g., pronunciation, level of education), rather than recognizing the multidimensional nature of HL. Third, some measures of HL were used in an inconsistent manner across studies, making comparisons of the findings difficult. For example, the original four categories of the REALM (i.e., 0–3rd grade, 4th–6th grade, 7th–8th grade, 9th grade and above) were used in some studies [22,33–37], but were reduced to three [38–41] or two [14,15,42–47] in others – with some loss of information and thus implications for the validity of the findings. In two studies, the REALM was treated as a continuous variable [16,48]. In another study, the authors [22] reported variation between the scores obtained on the REALM and the S-TOFHLA – raising questions about whether or not these instruments are measuring the same construct. All of these issues suggest caution when attempting to compare estimates of HL and interpret findings across studies.

3.4. Empirical relationships examined between HL and the three stages of the TDM process

Tables 2–4 present the findings according to their relevance to the three stages of the TDM process. The majority of studies ($n = 27$) examined relationships relevant only to the first (information exchange) stage of the TDM process (see Table 2). Eleven studies examined relationships relevant only to the second (deliberation) stage (see Table 3). Ten studies examined relationships relevant only to the third (deciding on the treatment to implement) stage (see Table 4). Five studies [18,24,25,43,45] examined relationships relevant to both stages 1 and 2. Two studies [9,26] examined relationships relevant to both stages 1 and 3. One study [46] examined relationships relevant to all three stages. In the sections that follow, the main findings from Tables 2–4 are summarized. Unique or unexpected findings are identified with an asterisk (*) in the tables.

3.4.1. Findings relevant to the information exchange stage of the TDM process

In the Charles et al. [3] TDM framework, information exchange can occur at any time throughout the medical encounter. Findings relating to relationships between HL and the type, amount, and flow of information that is exchanged between a physician and patient are listed in Table 2.

Seven studies reported on relationships between measures of patients' HL and different variables relating to patients': desire for information [34,42,45]; informational needs regarding disease, diagnostic tests, treatment, self-care, etc. [22]; question asking [30,43]; and information seeking habits [18]. In three of these five studies, no relationships were observed [22,34,45]. In the remaining studies, the findings were variable.

Three studies examined empirical relationships between patients' scores on one or measures of HL and patients' knowledge about prostate cancer [48] hormone therapy [24]; and pelvic floor disorders [25]. In two of these studies, positive relationships were observed between patients' HL scores and patients' knowledge scores [24,48]. In the remaining study, Spanish-speaking patients lacked knowledge about their condition irrespective of their HL score.

Ten studies examined empirical relationships between assessments of patients' HL and patients' understanding of information [9,14,15,17,19,23,33,35,50,51]. Across these studies, patients'

Table 4

Empirical studies included in the scoping review that have relevance to the deciding on the treatment to implement stage of TDM.

Reference	Characteristics and location of study population	Definition(s) of HL provided by authors	Instrument(s) used by researchers to assess HL	Empirical relationship(s) examined or reported on in study	Finding(s) (*unique or unexpected finding)
[41]	N=144 patients scheduled to see a general internist Mean age: 57 years United States (Boston)	None provided	REALM	Patients' REALM scores and patients' initial end-of-life-care preferences after hearing a verbal description of advanced dementia, and again after watching a 2 min video of a white patient with dementia	After hearing a verbal description, patients with low and marginal REALM scores were more likely to prefer aggressive care than those with adequate scores ($p < 0.0001$) After watching the video, patients with both low and high scores on the REALM changed their preferences toward less aggressive (or comfort) care. This change in preference was more pronounced amongst those with low and marginal scores on the REALM. Despite this change, the differences in preferences for care across low, marginal, and adequate scores on the REALM remained statistically significant ($p = 0.03$)
[40]	N=200 primary care patients Mean age: 75 years United States (Boston area)	None provided	REALM	Patients' REALM scores and patients' end-of-life-care preferences after: (1) hearing a verbal description of advanced dementia (control), or (2) watching a 2 min video of a patient with dementia (intervention)	Patients with adequate scores on the REALM chose comfort care with the greater frequency than those with low and marginal scores ($p < 0.001$)
[38]	N=76 primary care patients Mean age: > 70 years United States (rural Greensburg, LA)	None provided	REALM	Patients' REALM scores & patients' end-of-life-care preferences after: (1) hearing a verbal description of advanced dementia, or (2) hearing the same verbal description and then viewing a video decision aid	Higher REALM scores (i.e., \geq ninth grade) were associated with a greater likelihood of opting for comfort care (OR 12.1; 95% CI: 2.4–62.6)
[39]	N=146 patients scheduled to see a general internist Mean age: 57 years United States (greater Boston area)	None provided	REALM	Patients' REALM scores and patients' decision making uncertainty about care – before and after watching a video about advanced dementia	Patients' REALM scores was “a significant predictor of [decision making] uncertainty prior to the video” but “was no longer statistically significant in the prediction of [decision making] uncertainty after the video” (p. 32)
[31]	N=76 patients with early stage breast cancer Mean age: 51 years United States (Harris County Hospital District)	None provided	Level of education	Patients' level of education and patients' surgical treatment preference Patients' level of education and patients' level of decisional conflict about their surgical treatment preferences	All patients had low levels of education *Patients who viewed the decision aid ($n = 40$) were less likely than patients who were provided with printed material ($n = 36$) to indicate a preference for modified radical mastectomy (59.5% vs. 39.5%, $p = 0.018$) None of the patients ($n = 40$) who viewed the decision aid “were unsure about their surgical preferences” while 10.5% of those who were provided with printed material were unsure (p. 46)
[29]	N=205 general medicine outpatients United States (San Francisco, CA)	“Limited HL has been defined as having difficulty obtaining, processing, and understanding basic health information in order to make appropriate healthcare decisions” (p. 160)	S-TOFHLA	Patients' S-TOFHLA scores & and patients' uncertainty about (hypothetical) decisions made about life-sustaining treatment	In adjusted analysis, having limited versus adequate score on the S-TOFHLA (AOR 2.11; 95% CI: 1.03 to 4.33) “was independently associated with decisional uncertainty.” (p. 165)
[32]	N=102 patients with asthma Mean age: 28.9 years United States (Minnesota)	None provided	brief questions to identify patients with inadequate HL	Patients' answers to brief questions & patients' decisions to stop or decrease their everyday asthma medicines	No relationship observed

Table 4 (Continued)

Reference	Characteristics and location of study population	Definition(s) of HL provided by authors	Instrument(s) used by researchers to assess HL	Empirical relationship(s) reported on in study	examined or	Finding(s) ('unique or unexpected finding)
[46]	N = 84 patients with suspected ACS and evidence of myocardial ischemia United States (Atlanta, GA)	Ratzan and Parker's [12(p65)] definition	REALM	Patients' REALM scores and patients' responses to three questions: (1) Did the doctors ask you how you felt about different treatments? (2) Did the doctors make a decision without taking your preferences and opinions into account? (3) Did you feel pressured by doctors in the hospital to have a treatment you were not sure you wanted?		No relationship observed
[26]	N = 408 patients with Type II diabetes United States (San Francisco, CA)	"FHL is a measure of a patient's ability to perform basic reading and numerical tasks required to function in the health care environment" (p. 315)	S-TOFHLA	Patients' scores on the S-TOFHLA and patients' ratings of their experience with their doctor in regards to decision making		No relationship observed after patients' education and language were controlled for
[9]	N = 163 patients diagnosed with stage I/II primary breast cancer, completed surgery, and either had not received or had completed adjuvant chemotherapy United States	Ratzan and Parker's [12(p65)] definition	REALM	Patients' scores on the REALM and patients' responses when asked whether they believed that fictitious patients should have chemotherapy (response options: "no", "maybe," and "yes") after reading information provided in different risk communication formats		Compared to patients with lower scores on the REALM, patients with higher scores "less strongly endorsed chemotherapy when risk was low and more strongly endorsed chemotherapy when risk was high." (pp. 161–162)

understanding was variously defined and measured by researchers and the findings were also variable.

Two studies examined relationships between measures of patients' HL and: (1) the amount of counseling and direction provided by physicians to patients [30], and (2) physicians' use of unclarified medical jargon when communicating with patients [23]. Across these studies, the findings were variable. Another five studies investigated relationships between measures of patients' HL and patients' assessments of their health care providers' communication [16,26,36,46,47]. Across these studies, the findings were variable and, in some cases, contradictory.

3.4.2. Findings relevant to the deliberation stage of the TDM process

Deliberation is "the process of expressing and discussing treatment preferences" and, depending on the TDM approach adopted, can include the physician, the physician and the patient, or the patient alone [3(p656)]. Column five of Table 3 lists the empirical relationships that have relevance to the deliberation stage.

Eleven studies examined empirical relationships between assessments of patients' HL and patients' (or informal caregivers') perceptions about participation or involvement in decision making [18,20,24,25,27,28,37,43,45,46,52]. Across these studies, the findings were variable, and higher assessments of patients' HL were not always positively associated with patients' desired or perceived level of participation or involvement in deliberation.

In regards to the measurement of participation, or involvement, it is important to note that, in one study, the authors reported that their measure of participation had not been validated for use in their study [20]. The quantitative measures used to assess participation, or involvement, also relied on self-report data from participants, which, as some researchers noted, is susceptible to recall [53] and social desirability [54] response bias.

3.4.3. Findings relevant to the deciding on the treatment to implement stage of the TDM process

The decision on the treatment to implement refers to the process of selecting a specific treatment option to implement from the range of treatment options presented, and clarifying the respective roles of the physicians and patients in this process [3]. The empirical relationships that have relevance this stage are listed in Table 4. For comparative purposes, the findings from studies that involved the use of a patient decision aid (PDA) are summarized first and those that did not, second.

Five studies involved the use of a PDA to elicit, and/or examine, patients': preferences for care in the context of advanced dementia [38,40,41]; decision making uncertainty about care in the context of advanced dementia [39]; and breast cancer surgical treatment preference, and level of decisional conflict [31]. The following findings are worth noting. In two studies, patients with lower scores on the REALM expressed preferences for aggressive care more frequently than patients with higher scores on the REALM [40,41]. In one of these studies, the treatment preferences of some patients with both lower and higher scores on the REALM changed after exposure to a PDA (i.e., a verbal narrative and a 2 min video). These changes were: (1) more pronounced among patients with lower scores on the REALM, and (2) in the direction of less aggressive, or comfort, care [41]. Patients' reasons for these changes were not reported by the authors of this study.

It also is important to note the following. First, the PDA(s) used in these studies were not developed to reflect the needs of patients with diverse levels of HL. Second, level of education was used in one study as an indicator of HL despite the fact that: (1) the relationship between HL and level education has been disputed in the literature, and (2) three studies included in this review reported a lack of correlation, or congruence, between level of

education and level of HL [18,34,51]. Third, in four studies, the care or treatment preferences of patients were elicited using PDAs that reflected a medical condition that most, if not all, patients in the study population did not have at the time of the study [38–41]. The majority of patients in these studies, therefore, were making hypothetical treatment, or care, decisions. Fifth, it was not always stated whether or not a third party (e.g., family member or friend) was included when the PDA was being used; including, two studies that involved a small number of patients that had been diagnosed with dementia. The significance of third party involvement is thus unknown. Sixth, the research designs used in these studies did not: (1) allow researchers to elucidate the mechanism(s) responsible for the observed findings, and/or (2) involve blinding researchers to the intervention and control group. The findings associated with these studies should be interpreted with these limitations in mind.

In the five studies that did not involve the use of a PDA, patients' scores on a measure of HL were examined in relation to: patients' uncertainty about decisions made about life sustaining treatment after exposure to a hypothetical scenario [29]; patients' assessments of their doctors' decision making [26,46]; patients' endorsement of a particular intervention (chemotherapy) for a fictitious group of patients [9]; and patients' decision to stop or decrease their medications (for asthma) [32]. Across these studies, the findings were variable, largely non-overlapping, and non-comparable.

4. Discussion and conclusion

4.1. Discussion

This review sought to answer the question: What is known from the existing literature about the empirical relationship(s) between HL and the three stages of the TDM process? The findings from this review confirm the continued relevance of recommendations that more “research is needed to map the extent to which health literacy affects risk communication and treatment decision making in actual clinical settings” [9^(p165)] and explore “relationships between health literacy, information exchange, shared decision making and how health literacy can be described across cultures and social groups” [10^(p50)]. There is also a need to examine the strength and stability of relationships across the entire TDM process given that the majority of studies included in this review examined empirical relationships relevant only to the first (information exchange) stage of the TDM process.

The existing evidence is weakened by several factors; including, the: (1) predominance of cross-sectional, correlational studies; (2) multiple issues identified in regards to the measurement of HL; and (3) significant lack of overlap in terms of the empirical relationships that have been examined. Cross-sectional, correlational studies do not allow for causal inferences to be made or the directionality of the relationship(s) to be determined. While HL may influence the process of TDM, the process of TDM may also influence HL, and this has important implication for judgements about whether, and how, it might be appropriate to “tailor” PDAs or SDM more generally to people who “start” with different levels of HL. Future research in this topic area may benefit from the use of more responsive measures of HL and research designs that allow for the testing of causal relationships and the elucidation of the directionality of relationships. The use of longitudinal, mixed-methods research designs may also allow researchers to explain quantitative findings, understand the implications of context, and examine relationships, and/or outcomes, at different levels and over time.

The multiple issues that were identified in regards to the measurement of HL have been reported elsewhere [56,57] but have yet to be addressed in research examining HL and TDM. Future

research may benefit from the consideration, or incorporation, of Pleasant and colleagues [56] recommendations that the measurement of HL should: (1) be “explicitly built on a testable theory or conceptual framework of health literacy”; (2) explore core literacy skills (i.e., reading, writing, numeracy, speaking, and listening); (3) “measure on a continual, not a categorical basis”; (4) treat health literacy as a ‘latent construct’; (5) honor the principle of compatibility (i.e., use measures appropriate for the setting); and (6) “allow comparisons to be commensurate across contexts” [56^(p15–17)].

Pleasant and colleagues also recommend that measures be developed to test the HL skills of the information giver (e.g., the health care provider, system, or disseminator of a public health message). To date, as this scoping review confirms, little attention has been paid to the HL skills of providers, and influence of their skills on the TDM process. This gap is surprising given that the treatment decision making process must involve, at minimum, two parties (i.e., the patient and the physician) [3]. Conceptual models of HL also suggest that health care providers can influence patients' HL [55].

The lack of overlap that exists across studies in terms of the empirical relationships that have been examined is problematic because it prevents comparisons of the findings across studies, and reduces the generalizability of the findings. The lack of overlap also has important implications for the cumulation of knowledge in this topic area; particularly, for the aggregation of findings of studies of effectiveness. To increase the generalizability of the findings, there is a need to improve theorization and/or replicate studies in different settings, using different health care providers, and different patient populations – including patients that have been relatively neglected (i.e., those diagnosed with non-cancer-related diseases as well as patients who are younger than 50 years of age, less health literate, male, non-White, non-English- and non-Spanish-speaking, and residing outside of the U.S.).

Strengths of this review include: the adoption of the Arksey and O'Malley [11] framework to guide the review; the adoption of the Charles et al. [3] TDM framework to allow for a broad and inclusive approach to the topic of interest; the consultation with the Evidence-Based Practice Centre librarian and team at McMaster University to select the most appropriate databases and search terms for addressing the research question; the team approach taken to the development and testing of the relevance screening criteria used in this study; and the use of two reviewers to screen all records for inclusion in this review.

The exclusion of non-English records is a limitation of this review. Future research should seek to identify relevant studies that are published in languages other than English. The charting of the data from studies by the first author only is another limitation. To reduce the likelihood of error, the data entered into Tables 2–4 were checked multiple times by the first author to ensure their accuracy. Tables 2–4 were also reviewed by all of the authors of this review and modified, as necessary, to ensure clarity and completeness. Finally, the exclusion of studies that examined numeracy, but did not explicitly mention the term HL, or use one or use measures of HL, is a limitation. A separate review that focuses exclusively on numeracy is currently in progress.

4.2. Conclusion

The importance of HL to the three stages of TDM is not clear because of the knowledge gaps and multiple measurement-related problems that were identified in this review. Research is needed to address these gaps and problems in order to: (1) better understand the nature of (i.e., strength, direction, stability), and outcomes associated with, empirical relationships between HL and the three stages of TDM (both within and across patient populations and

over time), and (2) inform policy initiatives that seek to accommodate, in clinical practice, the needs of patients with diverse levels of HL.

4.3. Practice implications

There are currently many uncertainties about how SDM, or the design and use of PDAs, should respond to patients with different levels of HL.

Conflicts of interest

The authors do not have any actual or potential conflicts of interest to disclose.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <http://dx.doi.org/10.1016/j.pec.2014.11.004>.

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Appendix A: Search strategy used in MEDLINE

1. HL.mp. (1680)
2. exp HL/ (629)
3. reading ability.tw. (942)
4. numeracy.tw. (333)
5. or/1-4 (2854) ***[synonyms or proxies for HL]***
6. exp Decision Making/ (101749)
7. (decision-making or decisionmaking).tw. (48780)
8. Treatment options.tw. (24617)
9. Treatment choice.tw. (1380)
10. Treatment alternatives.tw. (1405)
11. exp treatment refusal/ (9890)
12. exp therapeutics/ (2991856)
13. exp decision support techniques/ (50121)
14. exp informed consent/ (32488)
15. exp patient participation/ (15439)
16. patient involvement.tw. (771)
17. patient acceptance of health care/
18. patient autonomy.tw.
19. patient-physician communication.tw. (321)
20. physician-patient communication.tw. (478)
21. physician-patient relations/ (54459)
22. information dissemination/ (7718)
23. exp Paternalism/ (2342)
24. or/6-23 (3235847) ***[words and phrases related to TDM]***
25. 5 and 24 (919)
26. limit 25 to English language and 2013 (888)

Appendix C: Search strategy used in Embase

1. health literacy.mp. (2198)
1. exp health literacy/ (638)
2. reading ability.tw. (1050)
3. numeracy.tw. (416)
4. or/1-4 (3537) ***[synonyms or proxies for HL]***
5. exp patient decision making/ (3199)
6. medical decision making/ (59330)
7. exp treatment refusal/ (9639)
8. treatment options.tw. (35113)
9. treatment choice.tw (1981)
10. treatment alternatives.tw. (1891)
11. decision aid*.tw. (1278)
12. PDA.tw. (6082)
13. decision support tools.tw. (433)
14. exp informed consent/ (50472)
15. patient participation/ (13479)
16. exp patient autonomy/ (1758)
17. exp paternalism/ (2102)
18. exp doctor patient relation/ (72669)
19. exp information dissemination/ (10340)
20. exp patient attitude/ (200706)
21. patient-physician communication.tw. (403)
22. physician-patient communication.tw. (581)
23. or/6-23 (405320)
24. 5 and 24 (711) ***[words and phrases related to TDM]***
25. limit 25 to English language (693)

Appendix C: Search strategy used in CINAHL

1. HL (search as a key word) (1255)
2. reading ability (search as a keyword) (245)
3. numeracy (search as a keyword) (210)
4. 1 OR 2 OR 3 (1658) [*synonyms or proxies for HL*]
5. Decision making, patient (explode) (8897)
6. Shared decision making (search as keyword) (736)
7. Informed decision making (search as keyword) (319)
8. Paternalistic decision making (search as keyword) (3)
9. Treatment options (search as keyword) (6476)
10. Treatment choice (search as keyword) (304)
11. Treatment alternatives (search as keyword) (235)
12. Therapeutics (explode) (619184)
13. Patient involvement (search as keyword) (449)
14. Refusal to participate (38)
15. Patient participation (search as keyword) (519)
16. Treatment refusal (2919)
17. Decision support techniques (explode) (957)
18. Consent (explode) (9948)
19. Patient autonomy (3640)
20. Physician-patient relations (13955)
21. Patient-physician communication (search as keyword) (116)
22. Physician-patient communication (search as keyword) (145)
23. 5-22 combined with OR (647976) [*words and phrases related to TDM*]
24. 4 and 23 (384) (Limit to English)

Appendix D: Search strategy used in Eric

1. All (HL) (2353)
 1. All (Reading ability) (16110)
 2. All (Numeracy) (2433)
 3. 1 OR 2 OR 3 (20631) [*synonyms or proxies for HL*]
 4. All (patient decision making) (460)
 5. All (Shared decision making) (1815)
 6. All (Shared decision-making) (1751)
 7. All (informed decision making) (1102)
 8. All (making informed decisions) (1104)
 9. All (Informed consent and decision making) (53)
 10. All (patient decision aids) (49)
 11. All (decision support tool) (755)
 12. All (Paternalism) (164)
 13. All (treatment options) (692)
 14. All (treatment alternatives) (1760)
 15. All (treatment choice) (1236)
 16. All (refusal of treatment) (115)
 17. All (patient involvement) (363)
 18. All (patient participation) (407)
 19. All (autonomy of patients) (92)
 20. All (Physician-patient relationship) (1042)
 21. All (physician-patient communication) (334)
 22. All (patient-physician communication) (77)
 23. 5-23 combined with OR (9323) [*words and phrases related to TDM*]
- 4 and 24 (137) * approximate count without duplicates

Preface

The study presented in Chapter 4 has been submitted to *Patient Education and Counseling*. This study reports the findings from numeracy-related studies that were not considered in Chapter 3. The findings show that the relationships between health literacy, numeracy, and treatment decision making are not clear due to significant gaps in knowledge and multiple methodological problems. The identification of these gaps and problems are priority areas for future research. The findings also show that health literacy and numeracy have largely been treated as separate concepts by researchers. These findings suggest that shared decision making policy initiatives seeking to accommodate patients with different levels of health literacy may not meet the needs of patients with different levels of numeracy.

Since the studies presented in Chapter 3 and 4 originated using the same research procedures, my role in each is identical. I consulted with Maureen Rice at McMaster University to identify the most relevant databases and search terms to use. I carried out all searches of academic databases, downloaded all of the resulting articles, developed the relevance screening criteria used to identify studies for inclusion, applied all of the relevance screening to articles, developed the data charting form, extracted relevant data from all studies, organized and analyzed the data, and wrote multiple iterations of the manuscript. Dr. Charles, Dr. Gafni, and Dr. Entwistle helped with the pilot testing of the relevance screening criteria. Dr. Charles assisted with the pilot testing of the data charting form. Dr. Malcolm Weir acted as a second reviewer during all levels of

relevance screening. Dr. Schwartz, Dr. McKibbin, and Dr. Yost provided feedback on my analysis and interpretation of the findings. They also provided feedback on multiple iterations of the manuscript. The version of the manuscript that was submitted to *Patient Education and Counseling* is presented in Chapter 4.

Chapter 4: Empirical Relationships Between Numeracy and Treatment Decision Making: A Scoping Review of the Literature

Abstract

Objectives: To determine what is known from the existing literature about empirical relationships between numeracy and the three stages of the treatment decision making process (information exchange, deliberation, and deciding on the treatment to implement). We also examined if, and how, numeracy was mentioned in relation to health literacy.

Methods: Four databases were searched and returned a total of 2,772 records. After de-duplication and three levels of relevance screening, 38 primary studies were included in this review.

Results: Relationships between numeracy and the information exchange stage have received greater attention than relationships between numeracy and the deliberation and deciding on the treatment to implement stages. The lack of overlap in the empirical relationships examined in studies, the measure(s) of numeracy used, and the characteristics of study populations, made findings difficult to compare. Multiple knowledge gaps and measurement-related problems were identified. Numeracy and health literacy have largely been treated as separate concepts.

Conclusion: The importance of numeracy to health literacy and to treatment decision making is unclear.

Practice Implications: Decision aids designed for patients with different levels of health literacy may not meet the needs of patients with different levels of numeracy. The numeracy skills of health professionals require attention.

1.0 Introduction

Internationally, there is a growing shift toward the promotion, and in some cases legislation, of shared decision making, in clinical practice [1,2]. This shift is notable given that multiple barriers to the implementation of shared decision making and patient decision aids have been identified [3]. One barrier which may limit patients' participation in shared decision making, or use of decision aids, is low numeracy. This barrier arises when, for example, health professionals communicate the results of medical tests, or the risks and benefits of treatment options, to patients.

Numeracy is defined as, “the ability to access, use, interpret, and communicate mathematical information and ideas, in order to engage in and manage the mathematical demands of a range of situations in adult life” [4^(p. 21)]. International assessments have found poor numeracy to be widespread in a number of countries [5]. Low numeracy has also been identified as a problem in both patients [6] and health professionals [7-9]. Patients who lack numeracy will have difficulties assessing the likelihood, and probability, of any risks and benefits associated with treatment options. Health professionals who lack numeracy will have difficulty explaining numerical information needed to help guide patients through difficult treatment decisions. As such, there is a need to attend to policy initiatives which seek to involve patients in treatment decision making, for example, through the use of shared decision making or patient decision aids.

One policy initiative that seeks to promote patients' involvement can be found under sub-section 936 of the 2010 U.S. Patient Protection and Affordable Care Act - titled “Program to Facilitate Shared Decisionmaking” [sic]. In this sub-section, provisions

appear which support the development and production of patient decision aids in ways that “present up-to-date clinical evidence about the risks and benefits of treatment options” in a manner that, among other things, “reflects the varying needs of consumers with diverse levels of *health literacy*” [10^(p. 1090, original italics)]. In another section of the Act, health literacy is defined as, “the degree to which an individual has the capacity to obtain, communicate, process, and understand health information and services in order to make appropriate health decisions” [10^(p. 1252)].

Unspecified, and unclear from the definition of health literacy provided, in the 2010 U.S. Patient Protection and Affordable Care Act is whether or not numeracy is considered to be a component of health literacy. This lack of specification is important since some measures of health literacy assess numeracy (e.g., Test of Functional Health Literacy Assessment of Adults, Newest Vital Sign), while others do not (e.g., Rapid Estimate of Adult Literacy in Medicine). It has also been identified that “numeracy is separate from literacy” and that “health numeracy is a significant and distinctive aspect of health knowledge and communication” [11^(p. 93)]. We thus sought to answer: *What is known from the existing literature about empirical relationships between numeracy and the three stages of the treatment decision making process (information exchange, deliberation, and deciding on the treatment to implement)?* We also examined if, and how, numeracy has been mentioned in relation to health literacy by researchers in this topic area.

2.0 Methods

To answer our questions, a scoping review was conducted of literature identified in a previous scoping review examining empirical relationships between health literacy and the three stages of the treatment decision making process [12]. While conducting the scoping review [12], a decision was made to report the findings related to numeracy-related studies separately. This decision was based on (a) the fact that some measures of health literacy assess numeracy, while others do not, (b) the explicit mention of health literacy, as opposed to numeracy, in sub-section 936 of the 2010 U.S. Affordable Care Act, and (c) statements made in the academic literature identifying numeracy as separate from literacy [10].

A detailed description of the methods has been published elsewhere [12]. In brief, 38 numeracy-related studies were identified after a search of four databases (see Table 1) and three levels of relevance screening (see Figure 1). Exclusion and inclusion criteria were developed and pre-tested by a team of researchers, then applied to all studies by LMW and MW. A data charting form was also pre-tested data and used by LMW to systematically collect, from all studies, information relevant for answering the scoping review question in this study.

Insert Table 1

Insert Figure 1

In the sections that follow, the temporal and geographic distribution of the 38 studies included in this review, the research designs and study populations used, and the

definitions and measures of numeracy adopted by researchers are summarized narratively. The empirical relationships that are relevant for answering the scoping review question are then identified according to their relevance to the three stages of the treatment decision making process (information exchange, deliberation, and deciding on the treatment to implement) [13]. Quality appraisal was not part of the scoping review method adopted [14], however, the limitations in the methods used in studies, and the gaps in the existing literature, are identified.

3.0 Results

3.1 Temporal and geographic distribution of the 38 studies

All of the studies included in this review were published between the years 2003 and 2013. The majority, however, were published in the years 2010 ($n = 8$ or 21%) and 2011 ($n = 13$ or 34%). In terms of their geographic distribution, the majority of studies were conducted in the United States ($n = 24$ or 63%). Three (8%) studies were conducted in Germany. Two (5%) studies were conducted in both New Zealand and Canada. Only one study was conducted in each of the following countries: Switzerland, the Netherlands, Spain and Italy. Three (8%) studies were conducted in more than one country.

3.2 Research designs and study populations

Cross-sectional studies were the most prevalent ($n = 20$ or 53%), followed by experimental ($n = 15$ or 39%), and qualitative studies ($n=3$ or 8%). Hypothetical scenarios (or conditions) were used with participants in 18 (47%) studies [11,15-31].

Across studies, the number and socio-demographic characteristics of the participants recruited by researchers varied. Individuals who were white, American, female, 40 years of age and older, and possessed higher levels of education appeared to be recruited more frequently in studies than their non-white, male, younger, and less educated counterparts.

3.3 Definitions of numeracy

One or more definitions of numeracy were provided in 26 (68%) studies included in this review (see column 3 of Tables 2-4). A comparison of these definitions revealed both similarities and differences. The ability to understand, or a synonym for understanding (i.e., comprehend, interpret, grasp), was mentioned in 21 definitions. This ability was, however, mentioned in reference to different things; for example, numbers [15,16,32], mathematical concepts [33], numerical concepts [17], risk information [34], “an aggregate statement about treatment outcomes” [32^(p.172-3)], “numbers and numeric concepts” [36^(p.705)], “quantitative information about health” [37^(p.337)], “quantitative information about uncertain outcomes” [38^(p.140)], statistical information [18], and “concepts of risk, probability, and the communication of scientific information” [39^(p.502)].

Some definitions went beyond simply the understanding of different types of numerical information, to its application; for example, to use [16,32,37,40]; apply [33]; “use and attach meaning to” [15^(p.30)], manipulate [38]; and make decisions [18]. Three definitions specified different contexts in which the understanding and use of different types of numerical information was believed relevant, but most did not. These contexts

include, “in daily life” [32^(p.163)], “in the context of health” [36^(p.705)], and “in the context of taking care of one’s health” [36^(p.705)].

Two definitions of numeracy made explicit references to literacy, as opposed to health literacy. In one study [19], numeracy was defined, in brackets, as quantitative literacy. In another study, numeracy was defined as “the mathematical counterpart to literacy” [41^(p. 611)].

3.4 Measures of numeracy

Across studies, numeracy was assessed in an inconsistent manner by researchers (see column four of Tables 2–4). Schwartz et al.’s [42] measure of numeracy was the most commonly used [16,21,22,34,43-45]. This measure consists of three questions to assess an individual’s: (a) basic familiarity with probability, using a question involving a coin toss; (b) ability to convert a percentage (1%) to a proportion (10 in 1000), using a lottery-related question; and (c) ability to convert a proportion (1 in 1000) to a percentage (0.1%) using another lottery-related question. The total number of correct responses is used to produce an overall numeracy score. Schwartz et al.’s [42] measure was originally developed to examine women’s understanding of the benefit of screening mammography using a sample of American women with a median age of 68 years. In studies included in this review, Schwartz et al.’s [42] measure was used with prostate cancer patients [34], and in the context of cardiovascular disease [21,43], colorectal cancer [16], and genetic screening [22].

The Subjective Numeracy Scale, or SNS, was used in four studies [19,23,24,46]. The SNS “is a self-report measure of perceived ability to perform various mathematical tasks and preference for the use of numerical versus prose information” [47^(p. 663)]. Three studies [15,17,33] used a measure of numeracy developed by Lipkus et al. [48]. This measure assesses how well highly educated adults can (a) “discern differences in magnitudes of health risks”, (b) differentiate and perform simple mathematical operations on risk magnitudes using percentages and proportions”, (c) “convert percentages to proportions”, (d) “convert proportions to percentages”, and (e) “convert probabilities to proportions” [48^(p. 38)]. The remaining studies used a subset of items taken, adapted, or combined, from different measures of numeracy, or used a proxy for its measure. The reliability and validity of these measures were not clear.

Across studies, there was variability in terms of how data obtained from numeracy measures were handled. Median split analysis was used in four studies [17,19,23,34]. The use of median split analysis is discouraged except in cases when the results are highly skewed and when the division is made at a theoretically- or empirically-derived cut-point [49]. Three of the four studies that used median split analysis did not report whether or not the results were skewed, nor did they report the actual cut-points [19,23,24]. Another four studies [17,34,44,45], reduced participants’ numeracy scores to two categories.

3.5 Mention of health literacy in studies

The term health literacy appeared in 15 (39%) studies included in this review (see column 5 of Tables 2-4). In two of these studies, numeracy was identified as a

component of health literacy [32,40]. In two studies [31,33], health literacy was listed as a keyword, but not mentioned elsewhere. Two studies used a sub-set of items from a measure of health literacy to assess numeracy [50,51]. One study made reference to a model of health literacy, spoke of its limitations, and then went on to develop a framework for health numeracy [39]. In the remaining studies, health literacy and numeracy appeared to be treated as separate concepts by the authors.

3.6 Empirical relationships examined between numeracy and the three stages of the treatment decision making process

Tables 2-4 summarize the findings according to their relevance to the three stages of the treatment decision making process. The majority of studies (n=18 or 47%) examined relationships relevant only to the information exchange stage (see Table 2). Two (5%) studies [21,37] examined relationships relevant only to the deliberation stage (see Table 3). Five (13%) studies [18,20,34,46,52] examined relationships relevant to only the deciding on the treatment to implement stage (see Table 4). Four (11%) studies [36,40,41,53] examined relationships relevant to both the information and exchange and deliberation stages. Eight (21%) studies [19,22-24,28,33,38,43] examined relationships relevant to both the information exchange and the deciding on the treatment to implement stages. No studies examined relationships relevant to all three stages of the treatment decision making process. In the sections that follow, the main findings from Tables 2-4 are summarized. Findings that are unique (i.e., relative to other studies listed in the Table), or unexpected (i.e., as reported by the authors), are marked with an asterisk (*) in the Tables.

3.6.2 Findings relevant to the information exchange stage of the treatment decision making process

In the Charles et al. [13] treatment decision making framework, information exchange can occur at any time throughout the medical encounter. During this stage, the physician may communicate, among other things, to the patient, “the natural history of the disease, the benefit and risks (side effects) of various treatments” and “a description of the treatment procedure(s)” [13^(p. 654)]. The patient may choose to reveal information about their health history, lifestyle, and social context, as well their beliefs fears about their disease, and “knowledge of various treatment options” [13^(p. 654)]. The empirical relationships that have relevance to information stage of the treatment decision making process are listed in column 6 of Table 2.

Ten studies provided primarily written numerical information to participants in multiple formats to examine relationships between participants’ numeracy and participants’: ranking of explanatory modes of communication that would most likely encourage them to take preventative cardiovascular disease medication [43]; understanding (or comprehension) of risk or risk-related perception(s) [16,17,23,38,31]; verbatim and gist knowledge [24]; susceptibility to framing effects [15,27]; and ability to make diagnostic inferences. In five of these 10 studies, participants with lower numeracy were significantly more likely than those with higher numeracy to: exhibit framing bias [15,27]; prefer pictures over numbers for the communication of numeric information [43]; incorrectly identify the likelihood of death associated with different cancer treatments [23]; incorrectly answer questions related to verbatim and gist knowledge [35]; and report higher perceived risks [28].

Four studies examined the use of analogies for answering easy and difficult medical problems [29], a comparison scenario technique for distinguishing different levels of prenatal risk [30], a decision aid for improving factual knowledge of treatment benefit [33], and a decision aid for improving numeracy [54]. In two of these studies [30,33], participants' with higher levels of numeracy benefited significantly more than participants with lower numeracy. In one study [29], the use of analogies was helpful to participants with low numeracy for answering easy medical problems and to participants with high numeracy for answering difficult medical problems. In the remaining study [54], exposure to a decision aid benefited some patients (i.e., those who were already familiar with the information and understood the underlying message) significantly more than others (i.e., those who did not understand the underlying message and did not develop the ability to deal with absolute and relative risk statements), $p < 0.001$.

Two studies examined empirical relationships between participants' numeracy and participants' knowledge of genomic recurrence risk test [44], and knowledge of information communicated orally during a genetic counseling session [22]. In these studies, participants with higher levels of numeracy had significantly greater knowledge than those with lower numeracy. Four studies examined empirical relationships between participants' numeracy and participants' ability to accurately interpret graphical representations of breast cancer risk [11], perceptions of breast cancer survival [45], comprehension of common and uncommon colorectal cancer risk information [50], and ability to take a verbally provided quantitative cancer risk and report it correctly using visual displays [26]. The findings from these studies were variable, non-overlapping, and

largely non-comparable. The findings in one study [50] are notable in that associations between numeracy and understanding varied depending on the measure of numeracy adopted and the type of information examined (i.e., common vs. uncommon).

Two qualitative studies examined how participants assigned meaning to medical test results [41] and perceptions of health numeracy [39]. In these studies, participants had difficulty understanding, and attributed different meaning(s) and level of importance to, numerical information. The remaining studies in Table 2 examined, or reported on, empirical relationships between participants' numeracy and patients' perceptions of their health care providers' communication [32,36,39,40,51,53]. Across these studies, the findings were variable. The findings in one study are notable in that participants with lower *subjective numeracy* were significantly less likely (OR 0.63-0.73) to perceive high quality provider communication. However, participants with low *objective numeracy* were significantly more likely to perceive high quality provider communication (OR 1.51-1.64). The authors attributed this finding to: (a) the weak correlation observed between subjective and objective numeracy in the study sample; (b) the possibility that individuals with higher objective numeracy have higher expectations of health care providers in terms of their communication; and (c) measurement- and research design-related factors.

3.6.3 Findings relevant to the deliberation stage of the treatment decision making process

Deliberation is “the process of expressing and discussing treatment preferences” and, depending on the treatment decision making approach adopted, can include the

physician, the physician and the patient, or the patient alone [13^(p.656)]. In column 6 of Table 3, the empirical relationships that have relevance to the deliberation stage are listed.

Two studies examined empirical relationships between participants' numeracy scores and participants' preferences for autonomy in making decisions about taking medication to prevent a heart attack [21], and usual role in their interactions with medical doctors and the role they believed they should play [37]. In these studies, the preference for autonomy in decision making was significantly higher among participants who were more numerate.

Two studies examined empirical relationships between participants' numeracy and participants' perceptions about the extent to which health care providers had involved them in past decisions [40,53]. The findings were variable, and, in one study, contradictory [53]. In the remaining two qualitative studies, participants reported using medical tests to collaborate with healthcare providers when making medical decisions [41], and evaluate the value and cost of health [36].

3.6.2 Findings relevant to the deciding on the treatment to implement stage of the treatment decision making process

The deciding on the treatment to implement stage refers to the process of selecting a specific treatment option to implement from the range of treatment options presented and clarifying the respective roles of the physicians and patients in this process [13]. The empirical relationships that have relevance to this stage of the treatment decision making process are listed in column 6 of Table 4.

Two studies involved the use of a patient decision aid to elicit, or examine, participants' preferences for therapy that would yield the highest chance of cancer free survival [33] and preference for choosing their radiation dose (i.e., higher or lower) versus leaving it up to the physician to decide [34]. Numeracy was a significant predictor of choice of therapy in one study [34], but not in the other [33]. It is important to note that in the study where numeracy was not a significant predictor the authors expressed concern that, after exposure to the patient decision aid, 30% to 40% of participants did not correctly identify the treatment that would statistically maximize cancer-free survival [33].

In the remaining studies that did not involve the use of a patient decision aid, four studies presented information or options to participants using interactive graphics [28], scenarios [46], visual depictions versus abstract numbers [18], or multiple formats [23] to examine relationships between participants' numeracy and participants' intention to take preventive action [28], willingness to undertake risk associated with a treatment for sickle cell disease [18], treatment intentions (i.e., hormonal therapy, chemotherapy, combined therapy, no therapy) [23], and choice of cancer treatments with varying efficacies and out-of-pocket costs [46]. In these studies, the findings were variable and non-overlapping.

Five studies examined empirical relationships between participants' numeracy and participants' keenness to take preventative cardiovascular disease medication [43], willingness to take tamoxifen [52], ability to identify the treatment choice that would statistically maximize cancer-free survival [24], previous participation (or lack of

participation) in a Phase I trial [38], and whether or not parents' would have enrolled their child in a hypothetical pain treatment study [19]. The findings in these studies were variable, non-overlapping, and non-comparable. Two studies reported on empirical relationships between participants' numeracy and participants' choice of continuing in a current state of health versus an imaginary treatment that would completely cure the symptoms, but carried a risk of death [20], and decisional conflict related to BRCA genetic testing [22]. Across these studies, the findings were also variable and non-overlapping.

4.0 Discussion and Conclusion

4.1 Discussion

In this scoping review, we sought to answer: *What is known from the existing literature about empirical relationships between numeracy and the three stages of the treatment decision making process (information exchange, deliberation, and deciding on the treatment to implement)?* The findings from this review share both similarities and differences with those reported in a previous scoping review of empirical relationships between health literacy and the three stages of the treatment decision making process [12]. In both reviews, there was a lack of agreement over of the definition(s) and measure(s) of numeracy and health literacy adopted by researchers. Relationships relevant to the information exchange stage received more attention in both reviews than relationships relevant to the deliberation and deciding on the treatment to implement stages. In both reviews, there was little overlap in terms of the empirical relationships

examined – making comparison(s), and generalizations, of the findings difficult. White, female Americans were also featured more often in studies included in both reviews. Similar methodological problems were also identified in both scoping reviews. These methodological problems include questions about the reliability and validity of instruments used to assess numeracy and health literacy, as well as inconsistent measure and handling of these variables. Hypothetical scenarios, which may not reflect treatment decision making in actual clinical settings, were used in studies included in both scoping reviews. Self-report measures, that are susceptible to recall [55] and social desirability bias [56], were also used in studies included in both reviews to assess participants' involvement. All of these issues weaken the existing evidence and limit the extent to which it can inform relevant policy and practice.

One of the major gaps in knowledge that is common to both scoping reviews is the lack of attention paid to how health professionals' numeracy and health literacy skills influence (a) patients' numeracy and health literacy skills and (b) the relationships examined. As noted in the previous scoping review, treatment decision making must involve, at minimum, two individuals – the patient and the physician [13]. Given that poor numeracy has been identified as a problem in health professionals, the fact that only one study [25] included in this review assessed doctors' numeracy, is surprising.

The major difference across the two scoping reviews pertains to the design of studies included in each review. In this review, a higher proportion of studies employed experimental designs, whereas correlational studies dominated in the previous review [12]. Mixed-method designs were also more prevalent in the previous review that

focused on empirical relationships between health literacy and the three stages of the treatment decision making process [12].

In regards to the use of decision aids, equal attention was paid to their use in both scoping reviews. Notably, there were studies included in both reviews, where the decision aid did not perform as expected by the investigators (i.e., participants did not select the anticipated treatment). The reason(s) for the findings were, however, not explored by researchers with the participants themselves. It is also notable that, in two earlier systematic reviews that focused on the effects and effectiveness of patient decisions aids [57,58], the authors recommended that greater attention be paid to health literacy and numeracy in future research. The authors of these reviews did not, however, indicate how problems relating to the definition, measurement, and handling of health literacy and numeracy should be handled. The authors also did not identify the need to assess the level, and influence, of health professionals' numeracy and health literacy skills on the effects and effectiveness of patient decision aids, or vice versa (i.e., the influence of patient decision aids on health professionals' health literacy and numeracy skills). These are important gaps in knowledge that we need to address.

Given the similarities in the findings across the two scoping reviews, a number of recommendations for research that were made in the previous review [12] have relevance to this review. These recommendations include the need to examine empirical relationships with numeracy, as a dependent or independent variable across the all three stages of the treatment decision making process, and over time. There is also a need to address the methodological problems that undermine research in this topic area. In future

research, the replication of studies in different clinical settings, with different health professionals and patients, would help to increase the generalizability of the findings. The use of explanatory mixed-methods designs would help to explain, and place in context, unexpected findings studies that emerge in quantitative studies. Assessment of health care providers' numeracy and the influence of their numeracy on both patients' numeracy and the treatment decision making process would also be beneficial.

Secondary to our main research question, we examined, if, and how, numeracy was mentioned in relation to health literacy by researchers in the area of treatment decision making. Our findings suggest that numeracy and health literacy have largely been treated as separate and distinct concepts. In the previous scoping review that focused on health literacy [12], the most commonly used measure of health literacy in studies (i.e., the Rapid Estimate of Adult Literacy in Medicine) did not assess numeracy and was adopted in studies that involved the use of decision aids. In this review, studies involving the use of decision aids assessed only numeracy. As such, we cannot assume that attention to health literacy in studies automatically implies attention to numeracy, or vice versa. It is also possible that policy initiatives, such as those in the 2010 U.S. Affordable Care Act, may result in the production of patient decisions aids that reflect the needs of patients with different levels of health literacy, but do not meet the needs of patients with different levels of numeracy.

The strengths of this review include the adoption of the Arksey and O'Malley [59] framework, the consultation with a specialist librarian at McMaster University to identify the most appropriate databases and search terms, the team approach taken to the

development, and testing of the relevance screening criteria, and the use of two reviewers during the relevance screening process. The limitations of this review include the exclusion of studies not published in English, and the charting of the data by a single person (i.e., the first author). To reduce the likelihood of error, the findings reported in the tables were checked by the first author multiple times to ensure their accuracy. The findings from this review were also reviewed multiple times by all of the authors to ensure their clarity and completeness.

4.2 Conclusion

The importance of numeracy to health literacy and to the three stages of the treatment decision making process is not clear from the findings in this scoping review. More research is needed to address the methodological problems and knowledge gaps identified in this review; in particular, the level and influence of health professionals' numeracy and health literacy. By addressing these knowledge gaps, researchers can better understand the unique and shared contributions of patients' and health professionals' numeracy and health literacy to the three stages of the treatment decision making process. Knowledge of these contributions will, in turn, help policy makers to better understand, and respond to, the numeracy and health literacy needs of both patients and health professionals during the treatment decision making process.

4.3 Practice Implications

Patient decision aids that are designed to reflect the needs of patients with different levels of health literacy may not meet the needs of patients with different levels

of numeracy. Academic institutions that train health professionals, health policymakers, and clinical practice managers need to: (a) support the regular assessment of health professional's numeracy skills and provide training to meet existing deficits, and (b) ensure that health professionals are trained to communicate numerical information to patients in a manner that is easily and accurately understood by patients during the treatment decision making process [7,9]. Health professionals must actively seek to maintain and improve their own numeracy as well as the numeracy of their patients.

Conflicts of Interest

The authors do not have any actual or potential conflicts of interest to disclose.

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Figure 1: Flow chart illustrating the total number of records retrieved from four databases and the relevance screening process

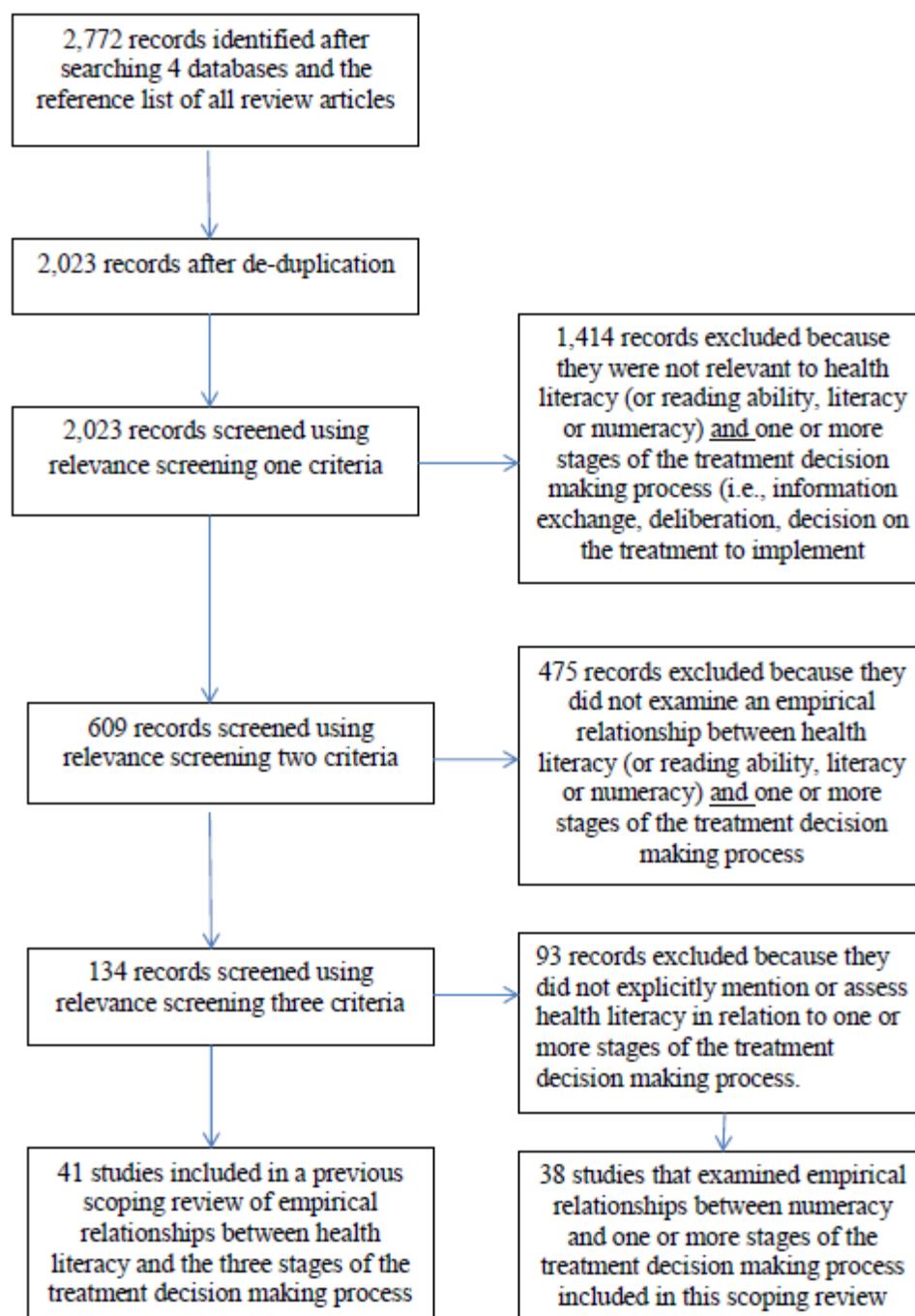


Table 1: Databases searched for the scoping review

Database Type	Database	Temporal Period Covered (start date reflects the year in which each database was established)
Academic	Medline (Ovid)	1946 – 31/12/2013
Academic	Embase	1980 – 31/12/2013
Academic	CINAHL	1982 – 31/12/2013
Academic	Eric	1966 – 31/12/2013

Table 2: Empirical studies included in the scoping review that have relevance to the information exchange stage of treatment decision making

Reference	Characteristics & location of study population (NR = not reported)	Definition(s) of numeracy provided by authors	Instrument(s) used by researchers to assess numeracy	Is health literacy mentioned?	Empirical relationship(s) examined or reported on in study	Finding(s) (*unique or unexpected finding)
43 (Goodyear-Smith et al., 2011)	N=934 Patients Age: majority (29.2%) between 51-60 years New Zealand (Auckland)	No definition provided	Schwartz et al. (1997)	No	Patients' numeracy & patients' ranking for numerical explanatory modes (i.e., relative risk, absolute risk, odds, numbers need to treat) that would encourage them to	Pictures were preferred over numbers by those who were less numerate (OR=1.1; CI, 1.01-1.2) More numerate patients more likely to rank relative risk first, over other explanatory modes of communication, for encouraging patients to take medication (OR = 1.2; 95% CI, 1.0-1.4)

Reference	Characteristics & location of study population (NR = not reported)	Definition(s) of numeracy provided by authors	Instrument(s) used by researchers to assess numeracy	Is health literacy mentioned?	Empirical relationship(s) examined or reported on in study	Finding(s) (*unique or unexpected finding)
					take medication and help them to make a decision	
28 (Ancker, Weber, & Kukafka, 2011)	N=165 Adults – 65 were patients Mean age: 32.0 (range 18-72) US	“...numeracy skills such as ability to calculate and manipulate percentage” (p. 130)	Adapted from Lipkus and others (2001)	Yes	Participants’ numeracy score & participants’: (1) risk feelings and (2) perceived helpfulness of interactive graphics (i.e., random graphic, sequential graphic, switch graphic, search graphic) for communicating risk	Low-numeracy participants reported higher perceived risks than high-numeracy respondents. These differences were “smallest in the search graphic” and “most exaggerated in the <i>random</i> and <i>switch</i> graphics” (p. 134) “...lower numeracy score correlated with higher perceived helpfulness of graphics; $r = 0.22$, $P = 0.002$.” (p. 134)
31 (Garcia-Retamero, Galesci, & Gigerenzer, 2010)	N = 117 Mean age: $n = 57$ (median age: 68 years); $n = 60$ (median age: 25 years) Germany (Berlin)	No definition provided	Schwartz’s (1997) measure, plus 1 additional question	Yes	Participants’ accuracy of risk understanding after reading information presented numerically vs. icon arrays	<i>Numerical presentation</i> : “...participants paid too much attention to numerators (i.e., the number of patients who died with and without treatment) and insufficient attention to denominators (i.e., the overall number of patients who did and did not receive the treatment)” (p. 678) <i>Icon arrays</i> : when “added to the numerical information, the denominator neglect disappeared. Icon arrays were helpful additions for both younger and older adults. These results held even when level of education was controlled in the analyses.” (p. 678)
17 (Keller & Siegrist, 2009)	N = 266 adult women	“the ability to process basic probability and	7 items from the Lipkus et al. (2001)	No	Participants’ numeracy & and participants’	Down Syndrome scenario: <i>Ratio format</i> : low- and high-numerate participants did not differentiate between

Reference	Characteristics & location of study population (NR = not reported)	Definition(s) of numeracy provided by authors	Instrument(s) used by researchers to assess numeracy	Is health literacy mentioned?	Empirical relationship(s) examined or reported on in study	Finding(s) (*unique or unexpected finding)
	Mean age: 47.7 years (SD = 15.2 years) Switzerland	numerical concepts” (p. 484)			assessments of risk after exposure to two fictitious scenarios in which the format of risk information varied (i.e., ratio, pictogram, Paling Perspective Scale)	high- and low-risk levels ($p > 0.05$). <i>Paling Perspective Scale</i> : low- numerate participants did not differentiate between high- and low-risk levels ($p > 0.05$). High-numerate participants in low- and high-risk groups behaved as expected (i.e., perceiving higher and lower risk levels appropriately). <i>Paling Perspective Scale</i> , low numerate participants did not differentiate between high- and low-risk levels ($p > 0.05$) High numerate participants were able to differentiate between and high- and low-risk levels ($p = 0.03$) Colon cancer scenario: <i>Ratio format</i> : Low- and high-numerate participants did not differentiate between high- and low-risk levels ($p > 0.05$). <i>Pictogram</i> : Low- and high-numerate participants did not differentiate between high- and low-risk levels ($p > 0.05$). <i>Paling Perspective Scale</i> : Low-numerate participants did not differentiate between high- and low-risk levels ($p > 0.05$). High numerate participants were able to differentiate between and high- and low-risk levels ($p < 0.001$).

Reference	Characteristics & location of study population (NR = not reported)	Definition(s) of numeracy provided by authors	Instrument(s) used by researchers to assess numeracy	Is health literacy mentioned?	Empirical relationship(s) examined or reported on in study	Finding(s) (*unique or unexpected finding)
24 (Hawley, Zikmund-Fisher, Ubel, et al., 2008)	N = 2,412 adults Mean age: 49 years US	No definition provided	Subjective Numeracy Scale	No	Participants' numeracy & participants' verbatim knowledge and gist knowledge when information presented in 1 of 6 numerical communication formats (i.e., pie chart, bar graph, pictograph, modified pictograph, modified pie graph, or table) Participants' numeracy & participants' perceptions of graph formats (i.e., how trustworthy, scientific, and effective)	Overall: Table format more likely than other formats to be associated with adequate verbatim knowledge ($p < 0.001$). Pie chart more likely than other formats to be associated with adequate gist knowledge ($p < 0.05$). <i>Higher numeracy participants:</i> scored significantly higher than lower numeracy participants on verbatim and gist knowledge regardless of graph type ($p \leq 0.05$). Bar graph did not significantly differ from table for conferring verbatim knowledge, while all other graphs formats did significantly worse than table ($p < 0.05$). None of the graph formats performed significantly better than the table for producing gist knowledge. <i>Lower numeracy respondents:</i> Bar graph and pictograph did not significantly differ from table for conferring verbatim knowledge, while all other graphs formats did significantly worse than table ($p < 0.05$). Pie graph and pictograph did significantly better than table for conferring gist knowledge ($p \leq 0.05$). <i>Perceptions of graph formats:</i> Higher numeracy participants rated each type of graph significantly higher than lower numeracy participants ($p < 0.05$) on all three constructs (i.e., how trustworthy, scientific, effective).

Reference	Characteristics & location of study population (NR = not reported)	Definition(s) of numeracy provided by authors	Instrument(s) used by researchers to assess numeracy	Is health literacy mentioned?	Empirical relationship(s) examined or reported on in study	Finding(s) (*unique or unexpected finding)
15 (Choi, Wong, Mendiratta et al., 2011)	N=95 Patients with chronic epilepsy Mean age: 39.1 (SD 13.6) years US (New York)	Numeracy, defined as” “the ability to comprehend and use numbers, is essential to understanding treatment risks.” (p. 29) and “the ability to comprehend, use, and attach meaning to numbers...” (p. 30)	11-question scale developed by Lipkus et al. (2001)	No	Patients’ numeracy score & patients’ susceptibility to framing bias after receiving information in mortality and then survival format	Patients with lower numeracy significantly more likely than patients with higher numeracy to exhibit framing bias (p = 0.014).
27 (Garcia-Retamero & Galesci, 2010)	N = 495 Germans and 492 Americans Age range: majority between 40-54 years old	“...people with low numeracy—who have difficulties grasping numerical concepts necessary for understanding risk communications” (p. 1323)	9 items taken from Schwartz et al. (1997) & Lipkus et al. (2001)	No	Participants’ numeracy & participants’ susceptibility to framing effects when presented with information (i.e., numerical, icon arrays, horizontal bars, vertical bars, or pies) expressing risk associated with a surgical procedure in either a negative (i.e., chances of dying) or positive ways (i.e., chances of surviving)	German and American participants with low numeracy were more susceptible to framing bias than those with high numeracy (p = 0.001). <i>Low numeracy participants:</i> Visual aids were not equally effective in reducing framing bias. “Pie charts and vertical and horizontal bars almost completely removed the effect of framing. Icon arrays, however, led to a smaller decrease in the framing effect.” (p. 1325) <i>High numeracy participants:</i> “the average difference between perceptions of the risk expressed in positive and negative terms was similar when they received and did not receive visual aids. Similar results were obtained regardless of which visual aid was provided.” (p. 1325-6)
16 (Han et al.,	N = 240 Adults	“people’s ability to understand	Schwartz et al. (1997) measure	No	Examined numeracy as a moderator of the	There was no significant main effects of numeracy on perceived risk or worry.

Reference	Characteristics & location of study population (NR = not reported)	Definition(s) of numeracy provided by authors	Instrument(s) used by researchers to assess numeracy	Is health literacy mentioned?	Empirical relationship(s) examined or reported on in study	Finding(s) (*unique or unexpected finding)
2011)	Mean age: 52 years US	and use numbers” (p. 355)			“effects of ambiguity (confidence interval v. point estimate) and representational format (textual v. visual) on cancer risk perceptions and worry” (p. 354)	
23 (Zikmund-Fisher, Angott, & Ubell, 2011)	N = 1,781 women Mean age: 54.3 (SD = 8.8) United States	No definition provided	Subjective Numeracy Scale	No	Participants’ numeracy & participants’ comprehension of risk associated with breast cancer treatment options when asked to consider options all at once vs sequentially	Numeracy was a significant predictor of comprehension of risk statistics. Both lower-numeracy and higher-numeracy participants showed significantly improved comprehension when questions were asked in a sequential choice process vs all at once. (*) “Lower numeracy participants (but not higher-numeracy participants) in the 1% risk reduction condition who were making decisions sequentially were significantly less likely than those in the standard presentation to correctly report that a person is more likely to die from cancer if taking hormonal therapy only versus both chemotherapy and hormonal therapy” (P = 0.002) (p. 83)
25 (Garcia-Retamero & Hoffrage, 2013)	N = 81 doctors and 81 patients Age: majority (95.1%) of doctors between	“Numeracy refers to people’s ability to understand and to deal with numerical information” (p. 28)	12 items taken from Schwartz et al. (1997) and Lipkus et al. (2001).	No	Doctors’ and patients’ numeracy & doctors’ and patients’ diagnostic inferences when information provided in different	(*) “...doctors and patients made more accurate inferences when information was communicated in natural frequencies as compared to probabilities” (p. 27) “visual aids boosted accuracy even when

Reference	Characteristics & location of study population (NR = not reported)	Definition(s) of numeracy provided by authors	Instrument(s) used by researchers to assess numeracy	Is health literacy mentioned?	Empirical relationship(s) examined or reported on in study	Finding(s) (*unique or unexpected finding)
	41-60 years; majority (50.6%) of patients between 61-85) Spain (Granada)				formats (i.e., natural frequencies vs probabilities, numbers vs. visual display)	the information was provided in natural frequencies” (p. 27) Differences “between doctors and their patients in accuracy of diagnostic inferences disappeared once their level of numeracy was statistically controlled for.” (p. 30).
29 (Galesic & Garcia-Retamero, 2012)	N = 517 Americans & 499 Germans Mean age: > 40 years US & Germany	“...numeracy enables greater depth of processing, decreases unintended effects of mood and framing on understanding of information, and improves decision making...” (p. 34)	11 items adjusted from scales developed by Schwartz et al. (1997) and Lipkus et al. (2001)	Yes	Participants’ numeracy & helpfulness of analogies for answering difficult and easy medical problems	(*) “...analogies were more helpful to high-numeracy participants for difficult problems and to low-numeracy participants for easy problems.” (p. 39) (*) “Different analogies were successful in different cultural contexts.” (p. 33)
30 (Pighin, Savadori, Barilla, et al., 2013)	N = 279 (181 currently pregnant & 98 pregnant in last 3 years) Mean age: 32 years, Italy	“numeracy skills (individual capacity to deal with probabilities)” (p. 49)	11-item scale of numeracy adapted from Lipkus et al. (2001)	No	Participants’ numeracy & participants’ ability to distinguish different levels of prenatal risk of chromosomal anomalies when presented with a comparison scenario	The comparison scenario technique was helpful for women with high numeracy skills, but had no effect on women with low numeracy skills.
44 (Richman, Tzeng, Carey, et al., 2011)	N = 78 Breast cancer patients Mean age: 58	No definition provided	Schwartz et al. (1997) measure	Yes	Patients’ numeracy scores patients’ knowledge scores about genomic recurrence risk test for	Women with higher numeracy scores had higher knowledge scores ($r=0.42$, $p \leq 0.001$)

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	years US (North Carolina)				women with early-stage breast cancer	
22 (Portnoy, Roter, Erby, 2010)	N = 246 Analog clients Mean age: 37 years US (Maryland & Utah)	“Numeracy plays an important role in client’s ability to learn information communicated during medical sessions, especially among clients who are otherwise regarded as literate” (p. 131)	Schwartz et al. (1997) measure	Yes	clients’ numeracy & clients’ knowledge of oral information communicated during a BRCA ½ genetic counseling session	Numeracy was positively associated with knowledge score (beta co-efficient = 0.275, $p < 0.001$) after adjusting for a number of variables.
33 (Lipkus, Peters, Kimmick, et al., 2010)	N=105 Breast cancer patients pooled across 2 studies Mean age: 56 years United States	“facility with understanding and applying mathematical concepts ¹¹ ” (p.464)	11- item measure from Lipkus et al. (2001)	Yes	Patients’ numeracy and patients’ factual knowledge of treatment benefit after exposure to a decision aid	More numerate patients were significantly more likely to correctly identify combined therapy as yielding the highest chance of cancer free survival (OR = 1.36; 95% CI = 1.12, 1.64). “Those with average or higher numeracy showed the expected relationship between perceived and estimated treatment benefit, whereas those with lower numeracy demonstrated no differences in perceived benefit across different levels of estimated benefit, $F(5, 91) = 2.7$, $P = 0.026$, adjusted $R^2 = 0.08$, $b = 0.005$, $P = 0.038$ for interaction.” (p. 469-470)
38 (Weinfurt, DePuy, Castel,	N = 328 Cancer patients that had been	“numeracy, to understand and manipulate	“A single item assessed how well patients understood a	No	Patients’ numeracy & patients’ expectations of benefit and harm	No relationship observed.

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et al., 2005)	offered participation in Phase I studies Mean age: 57.4 +/-12.2 years United States	quantitative information about uncertain outcomes.” (p. 140)	statement about the relative frequency of benefit from a hypothetical treatment...” (p. 142)		from standard and experimental treatments	
35 (Weinfurt, Castel, Sulmasy, et al., 2003)	N = 260 Cancer patients who had been offered participation in Phase I studies and had decided to participate Mean age: 57.6 +/-12.7 years US	“numeracy item measuring the ability to understand an aggregate statement about treatment outcomes” (p. 172-3)	“A single item assessed how well patients understood a statement about the relative frequency of benefit from a hypothetical treatment.” (p. 169)	No	Patients’ numeracy & patients’ expectations of benefit from experimental therapy	“...patients with higher expectations of benefit from experimental therapy were less likely to answer the numeracy question correctly [compared to those that did answer the question correctly, p = 0.038]” (p. 171)
60 (Schachter, Tharmalingam, & Kleinman, 2011)	N = 58 ADHD adolescents and parents & N = 64 controls Mean age: 14 years Canada	NR	WRAT 3 (mathematical skills)	No	Participants’ mathematical achievement & participants’ understanding of ADHD, the benefits and risks of stimulant medication, as well as the alternative treatment of behavior therapy or counselling	Participants’ mathematical achievement highly associated with participants’ understanding in all groups.

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54 (Kasper, Kopke, Muhlhauser, et al., 2006)	N = 169 Patients with multiple sclerosis Mean age: 44 +/- 11 years Germany	“public innumeracy’ according to which people are lacking competences in dealing with numbers and proportions.” (p. 57)	“three items which differentiated patients’ understanding of event rates” (p. 58) - a control event rate, an experimental event rate, and an absolute risk reductions -	No	Patients’ numeracy before and after exposure to a decision aid	Numeracy improved ($p < 0.001$) after exposure to the decision aid. However “99 of 169 patients did not complete the numeracy task correctly.” (p. 56)
11 (Brown, Culver, Osann, et al., 2011)	N = 120 Women with a personal or family history of breast cancer Mean age: 45.6 years US	“the degree to which individuals have the capacity to access, process, interpret, communicate, and act on numerical, quantitative, graphical, biostatistical, and probabilistic health information needed to make effective health decisions”(p. 93)	6-question numeracy scale derived by combining two previously validated 3-question numeracy scales	Yes	Participants’ numeracy score & participants’ graphicacy (i.e., ability to accurately interpret graphical representations of breast cancer risk)	Numeracy was significantly associated with accurate graph interpretation ($r = 0.665$, $p < 0.001$) Numeracy was the sole significant predictor of graphicacy and explained 41% of the variation in graphicacy scores.
19 (Tait, Zikmund-Fisher, Fagerlin, et al., 2010)	N = 4,685 Parents who had at least one child younger than 18 years Mean age: 39 years US	“Numeracy (quantitative literacy)” (p. e1477)	Subjective Numeracy Scale	No	Parents’ numeracy and parents’ gist (essential) and verbatim (exact) understanding and perceptions about the risks and benefits of enrolling their child in hypothetical pain treatment study – after exposure to 1 of	“Parents with higher numeracy had greater gist and verbatim understanding of the risks and benefits of the research” (p. e1478) For each scenario, “parents with higher numeracy perceived the risks to be less and the benefits to be higher than those with low numeracy” ($p < 0.001$) (p. e 1478-9)

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					4 scenarios in which the risks/benefits varied	
45 (Haggstrom & Schapira, 2006)	N = 207 patients from general internal medicine clinics Age: majority between 50-69 years US (Wisconsin)	No definition provided	Schwartz et al. (1997)	No	Patients' numeracy & accuracy of patients' risk perception of breast cancer survival ("On average, when women get breast cancer what are their chances of living for 5 years or longer?")	In adjusted analyses, no association between numeracy and accuracy of perceptions of breast cancer survival.
50 (Donelle, Arocha, & Hoffman-Goetz, 2008)	N = 140 older adults Age: majority (65%) between 50-69 years Canada (Southern Ontario)	"the degree to which individuals have the capacity to access, process, interpret, communicate, and act on numerical, quantitative, graphical, biostatistical and probabilistic health information needed to make effective health decisions." (p. 1)	4 numeracy questions from the S-TOFHLA General numeracy (Schwartz et al., 1997 measure) Health numeracy (8 items from Lipkus et al., 2001)	Yes	Participants' numeracy & participants' comprehension of common (i.e., widely publicized and easily accessible) and uncommon (i.e., genetics) Internet-based colorectal cancer risk information	(*) <i>health-context numeracy</i> skill: predicted comprehension success of both common and uncommon online colorectal cancer pages. <i>basic (STOFHLA) numeracy</i> ability: predicted participants' comprehension of common online prevention information only. <i>general-context numeracy</i> skill: "predicted comprehension of the more challenging or uncommon information but not comprehension of the common colorectal cancer risk information." (p. 5)
26 (Wong, Perez-Stable, Kim, et al., 2012)	N = 1,160 primary care patients	No definition provided	An 8-item numeracy measure adapted from a published scale and modified items from	No	Participants' numeracy and participants' ability to take a verbally	Women who had higher numeracy were more likely to use icon arrays correctly for breast or colon cancer scenarios (p < 0.001) and cervical cancer scenario (p

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	Mean age: > 60 years US (California)		Lipkus (2007, 1999) – translated into Chinese and Spanish		provided quantitative cancer risk and report it correctly using visual displays (icon arrays and magnifying glass graphic)	<0.01)
41 (Perzynski, Terchek, Blixen, et al., 2013)	N = 307 patients with hepatitis C [HCV] Median Age: 42 years United States	“Numeracy is seen as the mathematical counterpart to literacy and includes abilities in counting, arithmetic, percentages and relative values.” (p. 611)	Not assessed – qualitative study	Yes	Described “...how [HCV] patients assign meanings to medical test results and use these meanings to justify their actions.” (p. 610)	“Narrators [patients] used numbers as a key health indicator. At the most basic level, narrators [patients] related the numeric counts and descriptive labels of their test results. The interpretations focused on how lab results changed over time, ranking test results and the extent to which these results were meaningful signs of changes in health or prognosis.” (p. 616) “...HCV patients grapple with available information to make sense of their illness. People interpret their test results with varying levels of expertise and draw upon sociocultural and scientific sources to create personalised meanings of their test results. Some may simply know their numbers and without knowing what they mean...” (p. 623)
39 (Schapira, Fletcher, Gilligan, et al., 2008)	N = 59 patients from three internal medicine clinic sites Age range: 40-74	“In the modern world, numeracy includes a range of skills that have in common a facility with manipulating and interpreting	Numeracy not assessed quantitatively	Yes	Patients’ perceptions of health numeracy	Participants sometimes misinterpreted statements of probability, chance and odds. The terms “probably” and “probability” were often used interchangeably. “Some participants expressed an

Reference	Characteristics & location of study population (NR = not reported)	Definition(s) of numeracy provided by authors	Instrument(s) used by researchers to assess numeracy	Is health literacy mentioned?	Empirical relationship(s) examined or reported on in study	Finding(s) (*unique or unexpected finding)
	United States	quantitative information such as calculations, understanding time, and the ability to interpret graphs and labels...Health numeracy also involves skills that allow one to understand concepts of risk, probability, and the communication of scientific evidence.” (p. 502)				<p>awareness of numbers as an imperfect indicator of a given health state, one that may not reflect how the patient experiences his or her health.” (p. 512)</p> <p>“Participants considered the use of numbers to convey the risk of disease and adverse events, treatment efficacy, and prognosis as important aspects of physician–patient communication.” (p. 509)</p> <p>“One salient affect that emerged was that of trust. Some expressed distrust of the use of numbers to communicate, suspicious that numbers could be used to misrepresent information for the purpose of persuasion. Numeric communication could also increase trust in a physician...” (p. 510)</p>
32 (Mangenello & Clayman, 2011)	N=661 Young adults Mean age: 23.3 years United States	“the ability to use and understand numbers in daily life” (p. 163)	“In general, how easy or hard do you find it to understand medical statistics?” (p. 166) – proxy for numeracy	Yes	Participants’ numeracy score & participants’ ratings of health provider communication	Compared to those with higher numeracy, participants with lower numeracy reported feeling “less able to rely on their provider (62% vs. 86%, $p<.0001$)” and were “less likely to say their provider made sure they understood information (70% vs. 88%, $p=.0001$) and helped with any uncertainty (51% vs. 75%, $p<.0001$), even when adjusting for other variables.” (p. 163)
40 (Smith, Wolf, & von Wagner, 2010)	N = 6,024 Adults	“Health numeracy, defined as “the skills needed to understand and use quantitative	“In general, how easy or hard do you find it to understand medical statistics?” – measure	Yes	Participants’ self-reported level of statistical confidence & participants’	The proportion of adults reporting that their healthcare provider only sometimes or never allowed them to ask questions, or checked for their comprehension, which

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	United States	health information.” (p. 170)	of statistical confidence		evaluations of patient-provider communication	was almost twice as high for participants with low compared with high statistical confidence. “Participants with low statistical confidence were significantly more likely to report the quality of their patient-provider interactions to be poor (OR= 1.67; 95% CI=1.43–1.96) controlling for other statistically significant and independent predictors...” (p. 176-8)
53 (Ciampa Osborn, Peterson, et al., 2010)	N = 3,286 mail & telephone respondents from the HINTS 2007 survey Mean age: 63.3 years United States	“Numeracy, defined as difficulty with the ability to use numbers in daily life,” (p. 158)	One subjective item adapted from scale developed by Woloshin et al. (2005) One objective item taken from Lipkus et al. (2001) and asked only of mail respondents	Yes	Participants’ subjective and objective numeracy & participants’ perceptions of provider communication (e.g., provider always allows health questions; provider always ensures understanding)	(*) In adjusted analyses, low <i>subjective numeracy</i> (compared to high subjective numeracy) was associated with lower odds of reporting that: provider always allows health questions (OR=0.62;CI: 0.50-0.77, p<0.001) and provider always ensures understanding (OR=0.64;CI:0.49-0.82, p<0.001). In adjusted analyses, low <i>objective numeracy</i> (compared to high objective numeracy) was associated with higher odds of reporting that: provider always allows health questions (OR=1.69;CI: 1.07-2.68, p< 0.05) and provider always ensures understanding (OR=1.54;CI 1.04-2.30, p<0.05)
51 (Jensen, King, Guntzviller, et al., 2010)	N = 131 low-income adults Mean age: 42.9 years (SD = 17.5)	No definition provided	4 numeracy items taken from the S-TOFHLA	Yes	Participants’ numeracy & participants’ satisfaction with healthcare provider’s	No relationship observed.

Reference	Characteristics & location of study population (NR = not reported)	Definition(s) of numeracy provided by authors	Instrument(s) used by researchers to assess numeracy	Is health literacy mentioned?	Empirical relationship(s) examined or reported on in study	Finding(s) (*unique or unexpected finding)
	United States (Indiana)				communication skills	
36 (Schapira, Fletcher, Ganschow, et al., 2011)	N = 49 Mexican-American adults from clinical & community sites Age range: 21-90 years United States (Milwaukee & Chicago)	“the ability to use numeric information in the context of health.” (p. 705) “the ability to use numbers and numeric concepts in the context of taking care of one’s health.” (p. 705)	Not assessed quantitatively	No	Participants’ desire to find meaning in numbers and time spent with health professional	“Participants described turning to friends or family, especially those with health care experience, to explain the meaning behind numbers. The desire for health professional to spend more time explaining the meaning behind numeric information was widely expressed. Participants wanted to understand the connection between a numeric health indicator and the underlying physiologic process.” (p. 708-709)

Table 3: Empirical studies included in the scoping review that have relevance to deliberation stage of treatment decision making

Reference	Characteristics & location of study population	Definition(s) of numeracy provided by authors	Instrument(s) used by researchers to assess numeracy	Is health literacy mentioned?	Empirical relationship(s) examined or reported on in study	Finding(s) (*unique or unexpected finding)
21 (Kenealey, Goodyear-Smith, Wells, et al., 2011)	N=934 Patients Age: majority (29.2%) between 51-60 years	None provided	Schwartz et al. (1997)	No	Patients’ numeracy & patients’ preference for autonomy in making decisions about taking medication to prevent a heart	Preference for autonomy (i.e., towards patient only making the decision) increased among patients who were more numerate (OR = 1.17; 95% CI: 1.05-1.29)

Reference	Characteristics & location of study population	Definition(s) of numeracy provided by authors	Instrument(s) used by researchers to assess numeracy	Is health literacy mentioned?	Empirical relationship(s) examined or reported on in study	Finding(s) (*unique or unexpected finding)
	New Zealand (Auckland)				attack	
37 (Galesic & Garcia-Retamero, 2011)	N= 1,009 adults in the U.S. & 1,001 adults in Germany Age range: 25-69 years United States & Germany	“...essential for the understanding and use of quantitative information about health” (p. 337)	9 items selected from Schwartz et al. (1997) and Lipkus et al. (2001)	No	Participants’ numeracy & (1) the usual role they play in their interactions with medical doctors, and (2) the role they believe they should play.	In adjusted analysis, people with low numeracy were more likely to report a preference for a more passive role than people with high numeracy (p = 0.35).
53 (Ciampa, Osborn, Peterson, et al., 2010)	N = 3,286 mail & telephone respondents from the HINTS 2007 survey Mean age: 63.3 years United States	“Numeracy, defined as difficulty with the ability to use numbers in daily life,” (p. 158)	One subjective item adapted from scale developed by Woloshin et al. (2005) One objective item taken from Lipkus et al. (2001) and asked only of mail respondents	No	Participants’ subjective and objective numeracy & participants’ perceptions of whether or not provider always involves patient in decisions	In adjusted analyses, low subjective numeracy (compared to high subjective numeracy) was associated with low odds of reporting that: provider always allows involves patients in decisions (OR=0.65;CI: 0.54-0.78, p<0.001) In adjusted analyses, low objective numeracy (compared to high objective numeracy) was associated with higher odds of reporting that provider always involves patient in decisions (OR=1.74;CI: 1.13-2.56, p<0.05)
40 (Smith, Wolf, von Wagner, 2010)	N = 6,024 Adults United States	“Health numeracy, defined as “the skills needed to understand and use quantitative health information.” (p. 170)	“In general, how easy or hard do you find it to understand medical statistics?” – measure of statistical confidence	Yes	Participants’ self-reported level of statistical confidence & participants’ response to the question: “During the past 12 months, how often did doctors, nurses, or other health professionals involve	<i>Confident in statistics vs. not confident in statistics:</i> Always (55.79% vs 44.30%) Usually (28.29% vs 29.20%) Sometimes (13.55% vs 19.35%) Never (2.37% vs 7.15%)

Reference	Characteristics & location of study population	Definition(s) of numeracy provided by authors	Instrument(s) used by researchers to assess numeracy	Is health literacy mentioned?	Empirical relationship(s) examined or reported on in study	Finding(s) (*unique or unexpected finding)
					you in decisions about your health care as much as you wanted? (Always, usually, Sometimes, Never)	
41 (Perzynski, Terchek, & Blixen, 2013)	N = 307 patients with hepatitis C [HCV] Median Age: 42 years United States	“Numeracy is seen as the mathematical counterpart to literacy and includes abilities in counting, arithmetic, percentages and relative values.” (p. 611)	Not assessed – qualitative study	Yes	Described “...how [HCV] patients assign meanings to medical test results and use these meanings to justify their actions.” (p. 610)	Patients “used information from medical tests to monitor their disease progression, collaborate with healthcare providers in medical decision-making and to make autonomous self-care decisions.” (p. 623)
36 (Schapira, Fletcher, Ganschow, et al., 2011)	N = 49 Mexican-American adults from clinical & community sites Age range: 21-90 years United States (Milwaukee & Chicago)	“the ability to use numeric information in the context of health.” (p. 705) “the ability to use numbers and numeric concepts in the context of taking care of one’s health.” (p. 705)	Not assessed quantitatively	No	Assessment of, and meaning attributed, to numbers by participants to numbers	<i>Theme: numeracy skills are applied broadly in health:</i> “Some applications relate to”, among other things, “assessing the credibility of evidence regarding treatment efficacy. Others relate to communication and medical decision making....Numeric information was also used to assess value and cost of health.” (p. 707)

Table 4: Empirical studies included in the scoping review that have relevance to the deciding on the treatment to implement stage of treatment decision making

Reference	Characteristics & location of study population	Definition(s) of numeracy provided by authors	Instrument(s) used by researchers to assess numeracy	Is health literacy mentioned?	Empirical relationship(s) examined or reported on in study	Finding(s)
43 (Goodyear-Smith, Kenealy, Wells, et al., 2011)	N=934 Patients Age: majority (29.2%) between 51-60 years New Zealand (Auckland)	No definition provided	Schwartz et al. (1997)	No	Patients' numeracy score and patients' willingness to take preventive cardiovascular disease medication	Keeness to take medication was not associated with numeracy level.
19 (Tait, Zikmund-Fisher, Fagerlin, et al., 2010)	N = 4,685 Parents who had at least one child younger than 18 years Mean age: 39 years United States	"Numeracy (quantitative literacy)" (p. e1477)	Subjective Numeracy Scale	No	Parents' numeracy and parents' gist (essential) and verbatim (exact) understanding and perceptions about the risks and benefits of enrolling their child in hypothetical pain treatment study	Parents with higher numeracy were "more likely to report that they would have enrolled their child in the [pain treatment] study had it been real (6.5 ± 3.0 vs 5.9 ± 2.9 , respectively, $P < .001$)."
28 (Ancker, Weber, Kukafka, et al., 2011)	N = 165 Adults – 65 were patients Mean age: 32.0 (range 18-72) United States	"...numeracy skills such as ability to calculate and manipulate percentage" (p. 130)	Adapted from Lipkus and others (2001)	Yes	Participants' numeracy & participants' intention to take a preventive action (not specified) after exposure to interactive graphics for communicating risk (random graphic, sequential graphic, switch graphic, search graphic)	Low-numeracy participants reported higher intention to take the preventive action (not specified) than high-numeracy respondents. These differences were "smallest in the search graphic" and "most exaggerated in the <i>random</i> and <i>switch</i> graphics" (p. 134)

Reference	Characteristics & location of study population	Definition(s) of numeracy provided by authors	Instrument(s) used by researchers to assess numeracy	Is health literacy mentioned?	Empirical relationship(s) examined or reported on in study	Finding(s)
20 (Schwartz, McDowell, & Yueh, 2004)	N = 18 Head and neck cancer patients Mean age: 59.6 years United States	“patient’s comfort with numerical concepts (“numeracy”)” (p. 401) “patients’ quantitative skills and comfort with numerical expressions (numeracy)” (p. 402)	3 items from Woloshin et al. (2001)	Yes	Correlations between patients’ numeracy scores & patients’ utility scores when assessed with 3 instruments (i.e., standard gamble, time tradeoff, and rating scale)	In the standard gamble: “The patient is asked to choose between continuing in his current state of health (with the associated symptoms) and an imaginary treatment that will completely cure the symptoms but carries a risk of death.” (p. 402) Spearman correlations between scores on the standard gamble and numeracy were stronger for numerate than non-numerate (0.90 vs 0.70).
18 (Patterson, Barakat, Henderson, et al., 2011)	N = 81 Parents of children with sickle cell disease (SCD) Mean age: NR for parents United States	“Numeracy,” the ability of participants to comprehend and make decisions based on statistical information” (p. 8)	Parents asked the highest risk at which they would hypothetically consent to the treatment to help their child (1/1000, 1/100, 1/33, 1/10, 1/5, and 1/3 in cases of Birth Defects; 1/1000, 1/100, 1/10, 1/5, 1/3, and 1/2 in cases of Cancer).	No	Parents’ willingness to undertake risk associated with hydroxyurea treatment when the presentation of risk information was varied according to display (visual depictions vs. abstract numbers) and severity	“the risk choices were consistent when the parent/guardian used pie charts or people histograms for cancer risk ($r=0.61$, $P<0.001$) and for birth defect risk ($r=0.76$, $P<0.001$).” (p. 7) No significant correlations for risk assessment between numerical representation and (1) pie charts and (2) people histograms. “Caregivers of children with sickle cell types that are seen as milder (SC, SB+, and other variants) were less willing to undertake risk than those with more severe types when presented with numerical information for both Cancer and Birth Defect scenarios.” (p. 8)
22 (Portnoy, Rotor, Erby,	N = 246 Analog clients	“Numeracy plays an important role in client’s ability to	Schwartz et al. (1997) measure	Yes	Participants’ numeracy and participants’	Decisional conflict unrelated to numeracy.

Reference	Characteristics & location of study population	Definition(s) of numeracy provided by authors	Instrument(s) used by researchers to assess numeracy	Is health literacy mentioned?	Empirical relationship(s) examined or reported on in study	Finding(s)
et al., 2010)	Mean age: 37 years US (Maryland & Utah)	learn information communicated during medical sessions, especially among clients who are otherwise regarded as literate” (p. 131)			decisional conflict when asked “how hard or easy it would be for them to make the decision to get BRCA ½ genetic testing if they were the client (or spouse) in the videotape.” (p. 132)	
33 (Lipkus, Peters, Kimmick, et al., 2010)	N=105 Breast cancer patients pooled across 2 studies Mean age: 56 years United States	“facility with understanding and applying mathematical concepts ¹¹ ” (p.464)	11- item measure from Lipkus et al. (2001)	Yes	Patients’ numeracy and patients’ choice of therapy after exposure to a decision aid	Numeracy was not a significant predictor of choice of combined therapy – the treatment yielding the highest chance of cancer free survival
24 (Hawley, Zikmund-Fisher, Ubel, et al., 2008)	N = 2,412 adults Mean age: 49 years United States	No definition provided	Subjective Numeracy Scale	No	Patients’ numeracy and patients’ ability to make a correct treatment choice (i.e., choose the medically superior treatment option)	Patients with higher numeracy were significantly more likely to make the correct treatment choice - Pill B (OR: 1.31, 95% CI: 1.05–1.62).
34 (van Tol-geerdink, Stalmeier, van Lin, et al., 2006)	N = 150 prostate cancer patients Mean age: 70 +/- 6 years Netherlands	“the ability to handle basic probability concepts” (p. 1107) “ability to recognise and understand	Schwartz et al. (1997)	No	Patient’s numeracy score & whether patient wanted to choose their treatment [higher or lower radiation dose], or leave the decision to the physician after	Patients with higher numeracy scores were nearly three times more likely than patients with low numeracy scores to accept to the option to choose their radiation dose (OR = 2.8, p = 0.02)

Reference	Characteristics & location of study population	Definition(s) of numeracy provided by authors	Instrument(s) used by researchers to assess numeracy	Is health literacy mentioned?	Empirical relationship(s) examined or reported on in study	Finding(s)
		risk information referred to as numeracy in the literature” (p. 61)			exposure to a decision aid. (The treatment preference was carried out.)	
38 (Weinfurt, DePuy, Castel, et al., 2005)	N = 328 Cancer patients that had been offered participation in Phase I studies Mean age: 57.4 +/-12.2 years United States	“ <i>numeracy</i> , to understand and manipulate quantitative information about uncertain outcomes.” (p. 140)	“A single item assessed how well patients understood a statement about the relative frequency of benefit from a hypothetical treatment...” (p. 142)	No	Patients’ numeracy & patients’ previous acceptance of Phase I trial enrollment	No differences in numeracy between patients who did and did not agree to participate in Phase I trial.
23 (Zikmund-Fisher, Angott, Ubel, 2011)	N = 1,781 women Mean age: 54.3 (SD = 8.8) United States	No definition provided	Subjective Numeracy Scale	No	Participants’ numeracy & participants’ treatment intentions (i.e., hormonal therapy, chemotherapy, combined therapy, no therapy)	<i>Higher-numeracy participants:</i> were “sensitive to the magnitude of the risk reduction conferred by chemotherapy with significantly higher intentions to take chemotherapy when the benefit is 5% instead of 1% ($X^2(1) = 36.11$, $P < 0.001$). However, they were “significantly <i>less</i> likely to prefer chemotherapy when treatment options were presented sequentially versus all at once in the standard presentation ($X^2(1) = 21.17$, $P < 0.001$).” (p. 84) <i>Lower numeracy participants:</i> “were (non-significantly) less likely to choose chemotherapy for a 5% risk reduction than for a 1% risk reduction.... By contrast, when lower-numeracy participants were presented with a series of yes/no choices, they were sensitive to the risk reduction

Reference	Characteristics & location of study population	Definition(s) of numeracy provided by authors	Instrument(s) used by researchers to assess numeracy	Is health literacy mentioned?	Empirical relationship(s) examined or reported on in study	Finding(s)
						magnitude, choosing chemotherapy significantly more often when the benefit was larger ($X^2(1) = 4.91$, $P = 0.03$).” (p. 84)
52 (Kaplan, Kim, Wong, 2012)	N = 417 female patients Mean age: 58.8 years United States (California)	No definition provided	Schwartz et al. (1997) and modified items taken from the National Assessment of Adult literacy	No	Patients’ numeracy & patients’ willingness to take tomoxifen	Women with a higher numeracy score were more willing than women with lower numeracy score to take tamoxifen ($p < 0.05$).
46 (Wong, Egleston, Sachdeva, et al., 2013)	N = 400 cancer patients Mean age: 61.1 years United States (Philadelphia & New Jersey)	No definition provided	Subjective Numeracy Scale	No	Patients’ numeracy & patients’ preferences for cancer treatments with varying levels of efficacy, toxicity, and cost.	Greater numeracy was associated with preferences for high survival.

Chapter 5: Conclusion

At a time when limited health literacy has been referred to by some researchers as a silent epidemic, and poor numeracy is a worldwide phenomenon, efforts to implement, and in some cases legislate, the use of shared decision making and patient decision aids in clinical practice are on the rise. Given the implications of these efforts for patients, practitioners, and policymakers, this doctoral research sought to answer: *How are health literacy and numeracy defined in the academic literature and what empirical relationship(s) do they have with the three stages of the treatment decision making process?* To answer this question, three separate, but inter-related, studies were undertaken.

In the first study, I conducted a systematic review to answer:

1. To what extent are different definitions of health literacy used in the academic literature?
2. What are the similarities and differences across definitions?
3. What kinds of interpretations are possible for the most commonly used definitions?

In the second study, I performed a scoping review to address:

4. What is known from the existing literature about the empirical relationships between health literacy and the three stages of the treatment decision making process (information exchange, deliberation, and deciding on the treatment to implement)?

In the third study, I undertook a second scoping review to determine:

5. What is known from the existing literature about empirical relationships between numeracy and the three stages of the treatment decision making process?
6. How has numeracy been mentioned in relation to health literacy by researchers in the area of treatment decision making?

In this concluding section, I summarize the main findings that emerged in these studies. I discuss the limitations of the research. I identify areas for future research. I also discuss the original contribution, significance, and potential implications of this research to the fields of health literacy and treatment decision making.

Main findings

Key findings from Study 1

Prior to undertaking this review, the extent to which different definitions of health literacy have been used in the academic literature was unknown. I identified 250 different definitions of health literacy that appeared in the academic literature between the years 2007 and 2013. I grouped these definitions into one of three categories – most commonly used definitions (n = 6), defined as those that appeared identically worded a total of five or more times in our sample; modified versions of the most commonly used definitions (n = 133), defined as those that were similar, but not identical, in wording to those identified in the first category; and “other” definitions (n = 111), defined as those that did not fit into either of the first categories. A critical analysis of the most commonly

used definitions found them open to multiple interpretations and reflecting underlying assumptions that are not always justifiable.

Based on the findings from Study 1, I argued that the existence of so many different definitions of health literacy in the academic literature, and the various interpretations possible for the most commonly used definitions, will pose significant challenges for the measurement of health literacy. The findings will also pose challenges for the development, implementation, and evaluation of health literacy-related policy initiatives, particularly, if those involved define and interpret health literacy differently. I further argued that action by policymakers on assumptions underlying definitions of health literacy – such as those that imply that a relationship exists between health literacy and the making of appropriate health decisions - may lead to the creation of policies and programs that conflict with existing policies and programs that support differing goals (e.g., wanting individuals to make “autonomous” health decisions versus health decisions that are externally defined as “appropriate”). Beyond these arguments, I raised the following important questions that all stakeholders (i.e., researchers, policymakers, health care practitioners, and patients) must grapple with:

1. Which definition(s) of health literacy should be adopted for the purposes of developing, implementing, and evaluating health literacy-related policy initiatives:
 - a. the definition(s) for which a valid and reliable empirical measure exists,

- b. the definition that is most commonly used in the academic literature,
 - c. the definition(s) that best fits with a given policy context and agenda,
 - d. or some combination of these and/or other criteria?
2. Who should be involved in interpreting the meaning of any given definition of health literacy that is adopted into policy – researchers, policymakers, and/or those who have the potential to be positively and/or negatively affected by the adoption, and interpretation, of any give definition (i.e., patients)?

In making the above determinations, I argued that, for the process to be both transparent and fair, a mechanism is needed to address power imbalances and conflicting interpretations and agendas that emerge across stakeholders (i.e., patients, researchers, health care practitioners, policymakers) during the process.

Key findings from Study 2

A number of statements have been made in the academic literature implying that health literacy influences, or is important to, treatment decision making. This notion has been reflected or reinforced in provisions found in the 2010 U.S. Patient Protection and Affordable Care Act. These provisions support the development, testing, and implementation of patient decision aids in ways that, among other things, reflect consumers with diverse levels of health literacy. To inform relevant policy, practice, and

future research, I conducted a scoping review of the literature to determine what is known from the existing literature about the empirical relationships between health literacy and the three stages of the treatment decision making process (i.e., information exchange, deliberation, and deciding on the treatment to implement). Numeracy studies were not included in this review, but were examined in a second scoping review (Study 3) because some measures of health literacy assess numeracy, while others do not. Health literacy, as opposed to numeracy, was also explicitly mentioned in the above-mentioned statements that imply a relationship with treatment decision, and in the provisions that appear in the 2010 U.S. Affordable Care Act.

In this scoping review, I identified a lack of agreement over the definition(s) of health literacy adopted by researchers in the area of treatment decision making. This finding both links to, and supports, the findings reported in Study 1. I found a lack of congruence between the definition(s) of health literacy adopted by researchers and the dimensions assessed by measures of health literacy used in studies. This finding has been reported elsewhere in the literature, but has yet to be addressed by researchers in the area of treatment decision making. I discovered a lack of overlap in the relationships examined across studies. This lack of overlap reduces the generalizability of the findings and has implications for the cumulation of knowledge in this topic area. I identified important gaps in the literature; specifically, the lack of attention to:

- relationships between health literacy and deliberation and deciding on the treatment stages of the treatment decision making process;

- certain populations (i.e., patients diagnosed with non-cancer-related diseases and patients younger than 50 years of age, white, non-English- and Spanish-speaking, and residing outside of the U.S.);
- the influence of the health literacy skills of health professionals on patients' health literacy and on the relationships examined.

I also uncovered a number of methodological problems; including, but not limited to, the over-reliance on study designs that do not allow causal inferences about relationships to be drawn. Based on these findings, I argued that the importance of health literacy to the three stages of the treatment decision making process is not clear.

Key findings from Study 3

Poor numeracy is widespread in many countries and has been identified as a problem in both patients and health professionals. These findings may limit the extent to which some patients can participate in treatment decisions; particularly, when numerical information about the risks and benefits of treatment options is communicated by health professionals to patients. In this study, I undertook a second scoping review to examine what is known about the empirical relationships between numeracy and the three stages of the treatment decision making process. I also examined if, and how, numeracy has been mentioned in relation to health literacy by researchers in the area of treatment decision making.

In this review, I found a lack of agreement over the definition, measurement, and handling of numeracy in studies. I identified important gaps in knowledge; including, but

not limited to, the lack of attention to the influence of health professionals' numeracy on patients' numeracy and the relationships examined. I identified a number of methodological problems that prevent causal inferences from being drawn. I also found that numeracy and health literacy have largely been treated as separate concepts by researchers in the area of treatment decision making.

Based on the findings in this study, I argued that importance of numeracy to health literacy and to the three stages of the treatment decision making process is not clear. I argued that attention to patients' health literacy in studies does not necessarily imply attention to patients' numeracy. I also argued that the development of patient aids that accommodate the needs of patients with diverse levels of health literacy may not meet the needs of patients with different levels of numeracy.

Limitations

Each of the three studies has limitations associated with their findings. In this section, I provide summarize the limitations in each.

Study 1

In Study 1, the definitions of health literacy extracted from the academic literature were confined to those appearing in English-language articles indexed in the Medline database between the years 2007 and 2013. The findings from this study are thus reflective of these limits and cannot be generalized to other languages or time periods. In regards to the critical analysis of the most commonly used definitions, interpretations beyond those of the authors are possible. Despite these limitations, the findings support

the argument that the large number of definitions that exist, and the different interpretations possible for the most commonly used definitions, pose significant challenges for the development, implementation, and evaluation of health literacy-related policy initiatives and for the measurement of health literacy.

Study 2

In Study 2, the search of the literature was restricted to English-language articles published in four databases (Medline, Embase, CINAHL, ERIC) up until December 31, 2013. As such, the findings from this review cannot be generalized to literature existing outside of these limits. The charting of data by the first author of the study is another limitation of the findings. To decrease the likelihood of error, the data charting tool was pilot-tested by two members of the research team. The first author checked the accuracy of all data multiple times. The data were also checked by members of the research team on multiple occasions for clarity and completeness.

Study 3

Studies included in Study 3 were purposely not included in Study 2. As such, the limitations associated with the search limits used in Study 2 apply to Study 3. Data from studies included in Study 3 were also charted by the first author. As in Study 2, the first author checked the accuracy of all data multiple times. Data contained in all tables and figures were also checked by the research team for clarity and completeness.

Future research

Without a doubt, the lack of agreement over the definition, meaning(s), and measure of health literacy and numeracy poses the greatest challenges to future research examining relationships with treatment decision making. Given the extent to which disagreement exists, it is unlikely that agreement on any single definition, meaning, and measure of health literacy and numeracy will be reached. It is, therefore, important that the meaning(s) of any adopted definition(s) of health literacy and numeracy in research, policy, research, and practice be made explicit. This includes making explicit (1) whether or not numeracy is considered to be a component of health literacy, and (2) assumptions underlying any adopted definition(s).

In regards to the measurement of health literacy, researchers within the field have put forth various recommendations. Some authors, for example, recommend the engagement of adult learners, patients, and policymakers in the instrument development process (Pleasant, McKinney, & Rikard, 2011). Others argue that a shared understanding of health literacy is needed for instrument development (McCormack, Haun, Sorensen, & Valerio, 2013). Neither of these recommendations, however, address, if, or how (1) varying and, potentially, conflicting interpretations of definitions; (2) imbalances in power that exist across stakeholders (i.e., patients, public, researchers, policymakers); and (3) assumptions underlying definitions of health literacy will, or should, be handled during the process. If the process is to be both fair and transparent, an explicit mechanism is needed to deal with these fundamental issues.

There is also a need to develop valid measures of health literacy and numeracy that: (1) are specific to the treatment decision making context context(s) in which they are used, and (2) assess the health literacy and numeracy skills of both patients and health care providers. Once valid measures are developed, researchers must use them in a consistent manner in order to facilitate the comparison of findings across studies.

In addition to the conceptual- and measurement-related issues identified above, more research is needed to better understand the relationships that exist (or do not exist) between health literacy and numeracy and the three stages of the treatment decision making process. To better understand these relationships, the knowledge gaps and methodological problems identified in Studies 2 and 3 must be addressed. This requires the use of research designs that allow causal inferences to be drawn about the direction, strength, and stability of relationships across all three stages of the treatment decision making process (i.e., information exchange, deliberation, and deciding on the treatment to implement). Studies must be replicated with different patients (particularly those that have been neglected in the past) and health professionals to determine the extent to which findings are generalizable. The level and influence of health care providers' health literacy and numeracy skills on patients' health literacy and numeracy, and on relationships examined, must also be determined.

The development and testing of conceptual models that seek to identify, and explain, the unique and shared contributions, or influence(s), of health literacy and numeracy to the three stages of the treatment decision making process is also needed. Using a case study approach (Yin, 2009), researchers could, for example, seek to answer:

How do breast cancer patients, health professionals, and policymakers define, interpret the meaning of, and perceive the importance of, health literacy and numeracy across the three stages of the treatment decision making process? Other types of patients that undertake treatment decisions could be substituted into this question. To answer this question, data would be gathered from all relevant parties, in actual clinical settings, and then triangulated to develop a conceptual model of health literacy and numeracy that spans the entire treatment decision making process.

When developing and testing conceptual models, it is important that researchers recognize, and make clear in each, that health literacy, numeracy, and treatment decision making are both context-dependent and dynamic concepts. As such, relationships that exist across these concepts will also be both context-dependent and dynamic. These features underscore the need to replicate studies using different patients, health care providers, and health care settings.

In summary, understanding the influence of health literacy and numeracy on the three stages of the treatment decision making process is made difficult by a number of challenges. These challenges include the definitional- and measurement-related issues that undermine research in this topic area. To move forward, explication of the meaning(s) of health literacy and numeracy is needed to inform instrument development. The dynamic and context-dependent nature of health literacy, numeracy, and treatment decision making also pose challenges for the study and generalizability of any relationships that may (or may not) exist across these concepts. Conceptual models that

are inductively derived, context-dependent, rigorously tested, and whose underlying assumptions are made explicit, are needed to guide future research in this topic area.

Based on the above recommendations, my future research agenda would proceed as outlined in the following nine steps.

Step 1: Specify the treatment decision making focus (e.g., breast cancer), and the clinical setting(s) of interest, in the research question. For example: *How do breast cancer patients, health professionals, and policymakers at the Juravinski Cancer Centre define, interpret the meaning of, and perceive the importance of, health literacy and numeracy across the three stages of the treatment decision making process (information exchange, deliberation, deciding on the treatment to implement)?*

Step 2: Use an exploratory case study approach (Yin, 2009), and maximum variation sampling, to answer the research question identified in Step 1. Triangulate the findings across patients, health professionals, policymakers and three stages of the treatment decision making process.

Step 3: Use the findings from Step 2 to:

- propose one or more shared definitions of health literacy and numeracy. The shared definitions should include elements that are common to definitions of health literacy and numeracy provided by patients, health professionals, and policymakers in Step 2.
- generate hypotheses, theories, and/or conceptual models of empirical relationships between health literacy, numeracy, and the three stages of the treatment decision making process. Any underlying assumptions, and/or objectives attached to these hypotheses, theories, and/or models should be explicated.

Step 4: Use a deliberative dialogue process (Canadian Council for International Co-operation, 2102) to:

- obtain feedback on the definition(s) of health literacy and numeracy proposed in Step 3. Feedback should be sought from patients, health professionals, and policy makers involved in Step 2.
- select and/or refine a shared definition of health literacy and numeracy for use in the context(s) identified in Step 1.
- identify, and make explicit, the meaning(s), underlying assumptions, and/or objectives (i.e., outcomes) attached to any selected definition(s) of health literacy and numeracy for use in the context(s) identified in Step 1.
- obtain feedback on any hypotheses, theories, and/or conceptual models generated in Step 3. Use the feedback to refine the hypotheses, theories, and/or models as necessary.

Step 5: Use an exploratory mixed-methods approach (Creswell & Plano Clark, 2007) to develop and validate measures of health literacy and numeracy that:

- reflect the definition(s) of health literacy and numeracy selected and/or refined in Step 4 and
- assess the health literacy and numeracy skills and abilities of both patients and health professionals in the context(s) identified in Step 1.

Step 6: Use the measures developed in Step 5 to empirically test the hypotheses, theories, conceptual models, underlying assumptions, and/or outcomes generated in Step 4. Use research designs that allow for the identification of:

- the strength, direction, and stability of empirical relationships across the three stages of the treatment decision making process and over time.
- the influence of health professionals' health literacy and numeracy on patients' health literacy and numeracy in each of the three stages of the treatment decision making process.
- the influence of the treatment decision making process on patients' health literacy and numeracy.

Step 7: Use the findings from Step 6 to refine existing, and/or develop new, hypotheses, theories, and models.

Step 8: Empirically test any new or refined hypotheses, theories, and/or models developed in Step 7.

Step 9: Replicate Steps 1 through 8 in different breast cancer treatment settings. Identify any similarities and differences in the findings across settings.

Original contribution and significance

The findings from this dissertation research advance knowledge by: (1) challenging previous ideas about the extent to which different definitions of health literacy exist in the academic literature, (2) balancing claims made in the academic literature about relationships between health literacy, numeracy, and treatment decision making, and (3) identifying priority areas for research. By doing so, the findings can help to inform relevant policy and practice and guide future research. In the sections that

follow, I identify the potential implications of the findings for policy, practice, and research.

Implications for Policy

Without specification of the meaning(s) of health literacy, it will make difficult the implementation, development, and evaluation of health literacy-related policy initiatives. It will also be difficult to hold policymakers accountable for any associated outcomes; particularly, if policymakers interpret definitions of health literacy differently from those responsible for the development, implementation, and evaluation of health literacy-related initiatives.

Overall, the existing evidence is extremely limited in terms of its ability to inform efforts to implement the use of shared decision making and patient decision aids in ways that accommodate the needs of patients with different levels of health literacy. The evidence also suggests that a focus on health literacy may result in the neglect of poor numeracy, which has been identified as a problem in both patients and health professionals.

Given the state of the existing literature, the provisions in Section 936 of 2010 U.S. Patient Protection and Affordable Care Act may have been: (1) based implicitly or explicitly, on claims made in the academic literature that were not fully supported by scientific evidence, and (2) adopted prematurely. As such, the implementation of these provisions has implications not only for patients in the U.S., but for patients in other countries where policymakers may, through a process of policy diffusion, adopt and implement similar initiatives.

Implications for practice

Given that low numeracy has been identified as a problem in both patients and health professionals, the lack of attention to the numeracy skills of health professionals has important implications for efforts to involve patients in treatment decision making. Health professionals may be ill-equipped to communicate numerical information about the risks and benefits of treatment options in a manner that is both accurate and easily understood by patients. The inability to communicate numerical information to patients in this manner puts health professionals at risk for violating their code of ethics; particularly, in regard to preventing harm to patients (American Medical Association, 2015; Canadian Medical Association, 2015).

Patients are often highly dependent on the health literacy and numeracy skills of health professionals for making treatment decisions that may ultimately affect their life expectancy, quality of life, financial status, use of other health resources, etc. Negative outcomes that are attributable to the low health literacy and/or numeracy skills of health professionals has the potential to undermine patient-provider trust, the patient-provider relationship, as well as public confidence in health care systems.

Implications for Research

The findings from this research suggest that researchers should exert caution when making claims about relationships between health literacy, numeracy, and treatment decision making. Users of research (i.e., researchers, health professionals, and policymakers) should also exert caution when interpreting or acting on claims made about

health literacy, numeracy, and treatment decision making. Going forward, researchers should seek to collaborate with a variety of stakeholders (i.e., other researchers, patients, health professionals, policymakers) to address the significant gaps in knowledge and multiple methodological problems identified in Studies 2 and 3. These gaps and problems must be addressed to better inform relevant policy and practice.

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